

	A	B	C	D
1				
2	Lower Willamette Group			
3	Portland Harbor RI/FS			
4	Draft Final Remedial Investigation Report			
5	Appendix G: BERA			
6	July 1,2011			
7				
8	Responses to EPA Comments on the Draft Portland Harbor RI/FS Baseline Ecological Risk Assessment			
9				
10	Comment Type	No.	Section	Page Line(s)
11	EPA Comments, Baseline Human Health and Ecological Risk Assessments. 12/23/09			
12				
13	Comment Type	No.	Section	Page Line(s)
14	General BERA	5		na
15				

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10	EPA Original Comment	Original Code
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13	EPA Original Comment	Original Code
14	<p><u>Evaluation of Localized Risk in the BERA:</u> All chemicals that exceed unacceptable risk should be carried forward into the draft Feasibility Study (FS). Information regarding the magnitude of the risk, the distribution of the risk and the strength of the measurement endpoint may be incorporated into the draft FS for the purpose of focusing remedial action decisions. However, it is important that the draft FS develop remedial action alternatives that meet the remedial action objectives for all chemicals that present an unacceptable risk to human health or the environment. The difference between identification of unacceptable risks in the BERA, and how those unacceptable risks may be used by EPA risk managers in making response or remedial decisions is given in an EPA Office of Solid Waste and Emergency Response (OSWER) directive. OSWER Directive 9285.7-28 P (Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites, October 7, 1999) is explicit in its Principle number 4 regarding characterization of site risks, and is repeated here to make clear to LWG what EPA requires for a risk assessment. "When evaluating ecological risks and the potential for response alternatives to achieve acceptable levels of protection, Superfund risk managers should characterize site risks in terms of: 1) magnitude; i.e., the degree of the observed or predicted responses of receptors to the range of contaminant levels, 2) severity: i.e., how many and to what extent the receptors may be affected, 3) distribution; i.e., areal extent and duration over which the effects may occur, and 4) the potential for recovery of the affected receptors. It is important to recognize, however, that a small area of effect is not necessarily associated with low risk; the ecological function of that area may be more important than its size." The failure to carry through to the completion of the BERA all chemicals identified as posing unacceptable risks to one or more ecological receptors, all lines of evidence directed to be used in the BERA by EPA and compounded by the subsequent development of PRGs for only a subset of chemicals posing unacceptable ecological risks in a document separate from the BERA, demonstrates the shortcomings of the BERA to provide the information needed by EPA risk managers to make remedial decisions at the Portland Harbor site. EPA should not have to review the details of a BERA with 18 attachments to identify those chemicals identified somewhere in the BERA as posing unacceptable risks. They should all be identified in both the executive summary and conclusion sections of the BERA. The penultimate BERA conclusion that only five chemicals (PCBs, dioxins/furans, mercury, PAHs, DDx compounds) are COCs is not consistent with LWG's own determinations throughout the BERA, and is unacceptable to EPA.</p>	
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5		green text
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10	LWG Comment Response	Reviewer
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13	LWG Comment Response	Reviewer
14	Please see response to 7-16-10 comments 5, 6, and 7. Risk conclusions for each receptor group (Sections 6.7, 7.6, 8.3, 9.3, and 10.3) and overall risk conclusions (Section 11) discuss implications of exceedances occurring over a small spatial extent.	jmk-cdm smith
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2	did best I could to date, may need discussion
3	TRV related, needs confirmation
4	to be completed or needs additional review by me and/or someone else
5	I have reviewed and provided response
6	I have not yet reviewed
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10	Comment Status
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13	Comment Status
14	partially addressed
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10	CDM Review Comment (page numbers refer to July 2011 clean copy)
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13	CDM Review Comment (page numbers refer to July 2011 clean copy)
14	The document was revised to include more lines of evidence and media, with additional COPCs carried through the BERA. However, not all of the chemicals posing risk or identification of chemicals posing localized risk are clearly identified and discussed. Additionally, risks and associated conclusions for some receptors are not based on home ranges provided by EPA in the Problem Formulation.
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8	Bob Dexter's review	
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10	New EPA Comment	New Comment Code
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13	New EPA Comment	New Comment Code
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	A	B	C	D
16	Comment Type	No.	Section	Page Line(s)
17	BERA risk calculation	12		na
18				
19				
20	Comment Type	No.	Section	Page Line(s)
21		13-9		na
22	EPA Comments 7/16/10			
	Comments on Section 9 of the RI Report	1	9.2.1 (Main Body of RI Report)	pp. 9-5
23				
24				
25	Comment Type	No.	Section	Page Line(s)
	General Comment	17	General	NA
26				
27				
28	Comment Type	No.	Section	Page Line(s)
	General Comment	23	General	NA
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31	Comment Type	No.	Section	Page Line(s)
	Specific Comment	30	ES	p. ES-2, Lines 19-26
32				
33				
34	Comment Type	No.	Section	Page Line(s)
	Specific Comment	37	Executive summary	p. ES-5, Lines 21- 22
35				
36				
37	Comment Type	No.	Section	Page Line(s)
	Specific Comment	46	Executive summary ES.3	p. ES-8, Lines 10-24
38				
	Specific Comment	48	Executive summary ES.3	p. ES-8, Lines 10-24
39				
	Specific Comment	49	Executive summary ES.4	p. ES-8, Lines 30- 32
40				
	Specific Comment	50	Executive summary ES.4	p. ES-8, Lines 39-40
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43	Comment Type	No.	Section	Page Line(s)
44	Specific Comment	59	3.2	p. 58, Footnote

	E	F
16	EPA Original Comment	Original Code
17	Technical errors in the calculation of risk to fish and wildlife from the ingestion of contaminated diets: There appear to be two technical errors in the calculation of risks to fish and wildlife from ingestion of contaminated diets: 1. Calculating dietary risks by adding together the two hazard quotients for risks from ingestion of contaminated prey and risks from ingestion of contaminated sediment. Total risks from all components of the diet should be calculated by summing the ingested doses from sediment and contaminated prey ingestion, then calculating a single hazard quotient combining risks from the two dietary fractions. The equation for this was given as Equation 1 on page 40 of the February 15, 2008 BERA problem formulation. It appears that the hazard quotients from the two dietary fractions were summed to obtain total risk, rather than the correct approach of summing the two ingested dose estimates, then calculating a single hazard quotient. EPA does not object to quantifying risks separately from sediment ingestion and contaminated prey ingestion, as this provides useful information. However, the total dietary risk calculations should be corrected as described earlier in this comment. 2. In the situation where only one of the two dietary fractions (either sediment or prey) has a hazard quotient > 1, the BERA shows the final HQ as only the HQ from the pathway with HQ > 1, not the sum of both HQs. This is not correct, total risk is that from the sum of ingested doses from sediment and prey. The LWG approach underestimates total dietary risks. Another problem with the BERA approach is the situation where both sediment and prey ingestion HQs are between 0.5 and 1.0, in which case the BERA drops both dietary fractions and concludes that chemical does not pose a risk. Could have a situation where prey HQ = 0.7 and sediment HQ = 0.7, for example, yielding a total HQ of 1.4 and a chemical of concern. The BERA approach would not identify such a chemical as a COC at all. Dietary ingested doses must be summed before calculating the total dietary HQ, even when both individual components of the diet (i.e. sediment and prey) have individual HQs < 1. The water TRV for dioxin continues to be mistakenly listed as 0.0001 ug/l. The correct water TRV for dioxin is number is 0.00001 ug/l. The correct value can be found on page B-10 of the EPA water quality criterion document for dioxin which can be found at the following website: http://www.epa.gov/waterscience/criteria/library/dioxincriteria.pdf The same value is also provided in the summary table of all aquatic life table of the 1986 Gold Book (Quality Criteria for Water 1986).	
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20	EPA Original Comment	Original Code
21	9. The dietary risk evaluation must be recalculated and the COCs and PRGs adjusted accordingly for use in the draft FS.	
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23	Although Section 7.5 of Appendix G states that lamprey were evaluated for exposure to TZW, the results of this evaluation are not clearly presented in the BERA. This is in part, because the TZW line of evidence was inappropriately dropped from the risk characterization and was not used to identify chemicals that pose unacceptable risk to aquatic receptors.	Issue
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25	EPA Original Comment	Original Code
26	Final risk characterization presented in Appendix G focuses on site-wide risk. Receptor exposure scenarios outlined by EPA in the problem formulation are not followed, and risk characterization is based on scenarios proposed by the LWG in this document. The result is that site-wide risk is emphasized, while localized risk is downplayed. As examples, note that many contaminants showing an HQ > 1 were dropped in fish, invertebrate, amphibian, and plants. PRGs were not developed for these compounds.	Issue
27		
28	EPA Original Comment	Original Code
29	Fish were assessed based on risk from individual contaminants, yet they are exposed to a complex mixture. Some of the mixture is composed of chemicals that have been shown to pose a risk based on a HQ > 1 and some of the mixture also consists of chemicals that were not identified as posing risk based on a HQ < 1 but may contribute to toxicity. Additivity of individual contaminant risk is a reasonable assumption, especially for chemicals acting via the same mode of action. As a result, sum the HQs for individual compounds to assess the risk from multiple contaminants.	Issue
30		
31	EPA Original Comment	Original Code
32	The statement regarding reduction or elimination of other contaminant risks as a collateral benefit of mink PCB remedies is unsupported by any information in the BERA, as it presumes a remedy for the site that has not been identified as of the date the draft BERA was submitted to EPA. Remediation of PCBs to reduce risk to mink may not reduce all risks from all contaminants to all receptors. One example of this is the Swan Island Lagoon shipyard, where tributyltin risks in multiple media and to multiple receptors are important, and may drive remediation in that location, even though tributyltin risks in the entire Portland Harbor site are largely limited to the Swan Island Lagoon shipyard, and are not as widespread as PCB risks. This is one of many areas in the draft BERA where there appears to be a preconceived notion that remediation of PCBs will address other contaminants that also pose a risk to ecological receptors. The BERA is not the place for the LWG to propose remedial decisions, and all language in the BERA proposing a remedy for a specific chemical, location(s) or media must be eliminated from the next draft of the BERA	Issue
33		
34	EPA Original Comment	Original Code
35	Despite the claim in the BERA text, a sample by sample scale for the exposure assessment is the ecologically relevant exposure scale for most benthic invertebrates and aquatic plants, whose combined species richness is likely higher than that of any other category of ecological receptors at the Portland Harbor site. Given the data density of water and sediment samples, it may also be the appropriate exposure scale for sculpin, at least at some locations within the site. Therefore, the sample by sample exposure scale is the ecologically relevant exposure scale for the numerically dominant taxa at the site. Modify the BERA text to reflect this.	Clarify
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37	EPA Original Comment	Original Code
38	The summary of ecological risks to the various fish feeding guilds and species used as target ecological receptors is not correct. Hazard quotients as high as 280 for lead in smallmouth bass tissues, 69 for tributyltin in the diet of sculpins, 31 for chromium in white sturgeon tissues, and 27 for total PCBs in carp tissues are not considered negligible risks by EPA. Remove this subjective statement from the BERA. Given the relatively limited number of fish samples and composites collected and analyzed, the potentially unacceptable risks to fish are found throughout the site. Refrain from making subjective statements about the magnitude of risks, and stick to the quantitative discussions of chemicals posing potentially unacceptable risks; which species have chemicals in their tissues, diets, or within the water column that pose potentially unacceptable risks; the uncertainties in these analyses; and the locations where risks are found	Issue
39	The executive summary fails to identify all the chemicals potentially posing unacceptable risk. Ten chemicals potentially posing unacceptable risk were identified for spotted sandpiper (copper, benzo(a)pyrene, dibutyl phthalate, Total PCB, PCB TEQs, dioxin/furan TEQs, dioxin/furan/PCB TEQs, aldrin, total DDEs, total DDXs), and five each for bald eagle and osprey egg lines of evidence (total PCB, PCB TEQs, dioxin/furan TEQs, dioxin/furan/PCB TEQs, 4,4'-DDE). Correct the text corrected to reflect these findings of the BERA.	Clarify, revise
40	The uncertainty in the bird egg risk analyses is largely due to the limited number of available eggs analyzed, and the few years worth of available egg data, some of which predates the listing of the Portland Harbor site on the National Priorities List, and less because of the biomagnification factors or field-derived TRVs. Revise the text here and in Section 8.1.1 to reflect this.	Expand
41	The executive summary fails to identify all the chemicals potentially posing unacceptable risk. Five chemicals potentially posing unacceptable risk were identified for mink (lead, total PCBs, PCB TEQs, dioxin/furan TEQs, total dioxin/furan/PCB TEQs). The count of three chemicals for river otter is correct, although the river otter list is total PCB, PCB TEQs and dioxin/furan/PCB TEQs. Clarify and correct the text to reflect this conclusion more accurately.	Clarify
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43	EPA Original Comment	Original Code
44	Include a brief explanation of why EPA and LWG agreed to perform the belted kingfisher risk analysis in the Uncertainty section instead of in the main risk characterization section.	Clarify

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16	LWG Comment Response	Reviewer
17	Regarding dietary risk calculations, please see response to 7-16-10 comment 128 Regarding the dioxin water TRV, please see response to 7-16-10 comment 79.	jmk-cdm smith
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20	LWG Comment Response	Reviewer
21	Please see response to 7-16-10comment 128.	jmk-cdm smith
22		
23	Please see response to 7-16-10 comments 41 and 99.	jmk-cdm smith
24		
25	LWG Comment Response	Reviewer
26	As resolved in the EPA-LWG non-directed comments meeting (LWG 2010b), potentially unacceptable risk has been defined as HQ > 1 calculated over the specified foraging area. Specifically, the exposure point concentration (EPC) has been calculated as the 95% UCL of the exposure medium (i.e., sediment, water, diet, tissue) calculated over the foraging area. The HQ has been calculated as the EPC divided by the appropriate TRV. Where insufficient data are available within the foraging area to calculate a UCL, the data rules defined in the BERA have been used to set the EPC (e.g., maximum concentration).	jmk-cdm smith
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28	LWG Comment Response	Reviewer
29	As resolved in the EPA-LWG non-directed comments meeting (LWG 2010b), the EPA problem formulation does not call for an analysis of chemical additivity other than for dioxin-like chemicals. In resolution of directed comments (uncertainties that underestimate risk), the LWG agreed to add a discussion of this uncertainty in the uncertainty analysis but not data analyses. This discussion is presented in Section 7.6.3.	jmk-cdm smith
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31	LWG Comment Response	Reviewer
32	Please see responses to comments 5, 6, and 7.	jmk-cdm smith
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34	LWG Comment Response	Reviewer
35	See response to comment 17.	jmk-cdm smith
36		
37	LWG Comment Response	Reviewer
38	Please see responses to comments 5, 6, 7, and 17.	jmk-cdm smith
39	The executive summary identifies the COPCs with HQs > 1 for each receptor group.	jmk-cdm smith
40	As resolved in the EPA-LWG non-directed comments meeting (LWG 2010b), the LWG agrees to use the newly available osprey egg data and these data have been fully characterized in the appropriate sections of the document (e.g., data, exposure assessment, and uncertainty analysis sections). No other bird egg data are available from within the Study Area that met the SCRA cutoff date and/or were of acceptable data quality for use in the risk assessment.	jmk-cdm smith
41	A revised summary of all potentially unacceptable risks (including the same contaminants summed in different ways such as total PCBs and PCB TEQ, dioxin/furan TEQ and total TEQ) is presented in the Executive Summary.	jmk-cdm smith
42		
43	LWG Comment Response	Reviewer
44	Additional information has been included in a footnote near the beginning of Section 3.2 to explain why the belted kingfisher was included in the uncertainty assessment.	jmk-cdm smith

16	Comment Status
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	not addressed
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20	Comment Status
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22	
	partially addressed
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25	Comment Status
	not addressed
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28	Comment Status
	not addressed
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31	Comment Status
	partially addressed
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34	Comment Status
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37	Comment Status
	partially addressed
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	partially addressed
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	partially addressed
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43	Comment Status
	addressed
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16	CDM Review Comment (page numbers refer to July 2011 clean copy)
17	
18	Based on the equations 7-4 and 7-5 presented on page 358, LWG appeared to not make the requested change. Two separate equations remain. The site calculations are not clearly presented so it is difficult to confirm, but LWG presents that they completed two separate calculations.
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20	CDM Review Comment (page numbers refer to July 2011 clean copy)
21	It appears as though not all of the EPA provided TRVs were included as directed (ex. Fish dietary TRVs) and the risk associated with diet was calculated as two separate calculations. These have not been revised in the Draft Final BERA,
22	
23	Section 9.2.1 of the RI has not been revised with respect to the lamprey. In the BERA, TZW is now more fully evaluated in Section 7.4. TZW chemical concentrations were compared to water TRVs to evaluate risks to benthic fish. Risk conclusions related to lamprey are presented in Section 7.4.3.2; however, risks are not clearly quantified and exposure is minimized in a lengthy uncertainty section (Section 7.4.3.2). Risk is again minimized -- stated to be overestimated--in Section 7.4.5.1. Acute toxicity tests completed for ammocoetes and showed sensitivity (7.3.4.2).
24	
25	CDM Review Comment (page numbers refer to July 2011 clean copy)
26	Although the document has been revised, localized risks are still minimized as not all HQs>1 are clearly identified by location. For some receptors, risks presented and/or conclusions made were not based on home ranges provided in the Problem Formulation.
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28	CDM Review Comment (page numbers refer to July 2011 clean copy)
29	Summed HQs (HI) were not identified in the revised document.
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31	CDM Review Comment (page numbers refer to July 2011 clean copy)
32	The third bullet on page ES-3 has been removed from the text; however, it has been replaced by a statement about the uncertainty associated with PCB risk estimates. The fourth bullet on page ES-3 provides HQs associated with risks to mink reproductive success, but the final sentence in the bullet ranks the uncertainties among birds, otters, and mink. Risk management statements remain throughout the document.
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34	CDM Review Comment (page numbers refer to July 2011 clean copy)
35	The statement was revised in the Executive Summary; however, this was not clearly completed for each receptor. For example, the revised document indicated that risks to the smallmouth bass were evaluated using the home range identified in the Problem Formulation and comment #199 (one mile). However, it does not indicate that only one side of the river was used per the Problem Formulation. An exposure area of 0.1 mile (using individual sampling locations) was identified for the sculpin as noted in Table 7-1. Risks are not clearly identified by location.
36	
37	CDM Review Comment (page numbers refer to July 2011 clean copy)
38	The text associated with the summary of risks to fish feeding guilds has been revised (page ES-10) but the revision includes risk management language/qualifying statements about risk and uncertainties. The discussion about the magnitude of risks has been revised but the subjective language remains throughout the document.
39	Section ES.4 has been revised but the text on pages ES-11 and 12 does not specify this level of detail. Currently risks to sandpiper based on exposure to PCBs and Total TEQ are discussed in the revised section. Risks to the bald eagle and osprey based on exposure to PCBs, TEQ, and DDx are described in the revised text of the Executive Summary.
40	The requested text has been removed from page ES-8 but a similar discussion was located in Sections 8.2.4.1 and 8.2.4.2. Uncertainties associated with field derived TRVs are located in these sections and in the green text box on page 544 in Section 8.2.3. Sections 8.2.4.1 and 8.2.4.2 describe additional uncertainties and that alternative TRVs were calculated and evaluated for these receptors.
41	The text has not been revised (page ES-11) to now include six, those listed in the comment plus aluminum.
42	
43	CDM Review Comment (page numbers refer to July 2011 clean copy)
44	Footnote 24 has been expanded to include an explanation and the uncertainty section is referenced (Section 8.1.5.2.2).

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16	New EPA Comment	New Comment Code
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20	New EPA Comment	New Comment Code
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25	New EPA Comment	New Comment Code
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28	New EPA Comment	New Comment Code
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31	New EPA Comment	New Comment Code
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37	New EPA Comment	New Comment Code
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43	New EPA Comment	New Comment Code
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	A	B	C	D
	Specific Comment	63	3.3	p. 61, Table 3-1
45				
46				
47	Comment Type	No.	Section	Page Line(s)
	Specific Comment	70	4.1.2	pp. 80-85
48				
	Specific Comment	71	4.1.2	p. 80
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51	Comment Type	No.	Section	Page Line(s)
52	Specific Comment	72	4.1.2	p. 82
	Specific Comment	75	5,7,8, 11	
53				
	Specific Comment	78	5.1	NA
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56	Comment Type	No.	Section	Page Line(s)
	Specific Comment	79	5.1	pp. 98-100
57				
	Specific Comment	81	5.2	
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60	Comment Type	No.	Section	Page Line(s)
	Specific Comment	85	6.4	p. 148, Text box
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63	Comment Type	No.	Section	Page Line(s)
	Specific Comment	86	6.5.1; 6.6.2	p. 173; p. 197
64				
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66	Comment Type	No.	Section	Page Line(s)
	Specific Comment	92	6.6.3	p. 202 Text box
67				

	E	F
	For omnivorous fish, correlation of lesion prevalence with areas of contamination is unlikely to yield useful information because the focal species identified have relatively large foraging ranges. This makes it difficult to draw linkages between exposure and effects. Therefore, evaluate the prevalence of lesions at ecologically relevant spatial scales, and compare this to regionally relevant background levels of lesions.	Revise
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47	EPA Original Comment	Original Code
	Several places in the BERA, starting with the discussion of mercury risks to eagles consuming fish on page 2 of the Executive Summary, discuss elevated risks in fish collected upstream of the Portland Harbor site. In any discussion of the upstream or regional data, acknowledge the differences between fish collected within the study area and those collected outside the study area. For example, EPA understands that many of the fish collected upstream of the site were larger and older than the fish collected from within the Portland Harbor site. This size difference may account in part for the relatively elevated concentrations of some contaminants in upstream fish, such as mercury and high log Kow chemicals such as PCBs and DDX. Given the absence of an approved workplan to collect upstream or reference area fish within the remedial investigation, include a discussion of the fish size effect on bioaccumulated chemical concentrations, or at least a pointer to this discussion in the food web model report. This issue is an uncertainty that may serve to underestimate site risks relative to risks in fish collected upstream of the site.	Issue
48		
	The metabolic ratios for DDT in tissue have a high percent of the DDT metabolite or DDD metabolite for some samples, indicating that there are recent sources of DDT into the River. No discussion of this observation is presented in the RI Report. In the RI Report, identify areas in the river where sources appear to be recent, based on metabolic ratios in fish and in sediment.	Issue
49		
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51	EPA Original Comment	Original Code
52	Describe what percent size difference was acceptable for compositing, and whether genders were mixed.	Clarify
	These tables are the summary tables that identify chemicals of concern from the various exposure scenarios and pathways. The use of "X" or filled circles to denote chemicals of concern does not provide sufficient information to risk assessors and managers to evaluate either the magnitude or spatial extent of the identified risks. Make these tables much more informative by including the following information for each identified chemical with a HQ >1: The total number of samples available, the number of samples where unacceptable risks have been identified, and the magnitude of the risks (e.g., maximum risk, risk range, and a central tendency measure of risk such as the mean or median hazard quotient). The comparison of the number of samples, locations or risk estimates with unacceptable risk compared to the total number of samples, locations or risk estimates with available data allows the reader to identify the contaminants with widespread or site-wide distribution of unacceptable risks vs. those where the spatial extent of risk is limited to one or a relatively few localized areas.	Issue
53		
	Present the substances for which no screening values are available in a table, and discuss these generally in the Uncertainty section.	Revise
54		
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56	EPA Original Comment	Original Code
	The dioxin (2,3,7,8-TCDD) surface water TRV as given in Attachment 5 (100 pg/L) is not correct. The correct TRV is 10 pg/L. EPA has made this comment previously and provided documentation. As a result, EPA is making this comment as a directed change. Further, this will require that the SLERA for dioxin in surface water and transition zone water be repeated to determine whether dioxin is carried through as a chemical of potential ecological concern (COPC) in surface water and TZW (applies to benthic invertebrates, fish, plants and amphibians).	Directed change
57		
	The refined screen for fish tissues should not be done on a species-by-species basis. Rather, all of the fish-tissue chemistry data should be aggregated and the maximum measured concentration of each COPC should be compared to the TSV for fish. If a substance is retained on this basis, then it should be evaluated in the BERA for each fish feeding guild. The results of that assessment will determine if the substance poses a potential risk to fish representing each feeding guild. The same approach should be applied to the invertebrate-tissue chemistry data.	Issue
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60	EPA Original Comment	Original Code
	Assessment based on individual samples. This approach is the appropriate exposure scale for numerous benthic invertebrates, aquatic plants, and possibly sculpin, all species which have no mobility or very limited size home ranges. Effects are to the local population or subpopulation of the target ecological receptor, not any one individual organism. The text box fails to discuss this aspect of the risk assessment, but instead tries to leave the impression that the risk assessment is overly conservative. EPA agrees that for some receptors with larger home ranges that encompass multiple sampling locations, calculation of an exposure point concentration based on multiple sampling results pooled in some manner (e.g., arithmetic or geometric mean concentration, 95% upper confidence limit of the mean, etc.) is appropriate, and this is discussed in the problem formulation in multiple locations. LWG was also given the option in the problem formulation to perform probabilistic risk assessments if desired, pending discussions and agreements with EPA on the approach, an option not pursued by LWG. EPA considers the February 15, 2008, problem formulation the minimum amount of assessment to be performed. The LWG has the option to pursue additional risk assessment approaches, including the use of procedures in Oregon's ecological risk assessment guidance.	Issue
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62		
63	EPA Original Comment	Original Code
	Tributyltin risks in surface water and transition zone water. It does not appear as though the LWG performed any comparisons of surface water and transition zone water concentrations of tributyltin to the EPA aquatic life criterion for tributyltin of 0.072 ug/L. EPA's analysis indicates that at least one surface water and one TZW sample exceed the tributyltin criterion for continuous concentration (CCC, commonly referred to as the chronic water quality criterion). Thus, the report should identify tributyltin as a chemical potentially posing unacceptable risk in surface water and transition zone water for all assessment endpoints where exposure to either surface water or TZW occurs. This includes benthic invertebrates, some fish feeding guilds, aquatic plants, larval amphibians, bivalves and decapods. Comparison of surface water and TZW tributyltin concentrations to the tributyltin CCC must be performed and the results presented for the above receptor groups in the appropriate sections of the BERA.	Clarify
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66	EPA Original Comment	Original Code
	Although the text box correctly describes some of the processes by which benthic infauna can reduce their exposure to contaminants in transition zone water, this behavior does not modify the chemical concentrations in TZW that elicit toxicity. It only changes their exposure. As numerous chemicals exceed the TZW TRVs, these chemicals with hazard quotients greater than or equal to unity must be identified as chemicals of concern for the site. The limited spatial coverage of the TZW sampling efforts means that unacceptable risks (or acceptable levels of risk) can only be quantified in the portions of the site with empirical TZW data. Ecological risks at the remainder of the site without empirical TZW samples are unknown, and are thus an uncertainty in the BERA with the potential for underestimating site risks. This possibility must be discussed in the BERA. EPA therefore does not agree with LWG's contention that TZW risks are overestimated in the BERA. For immobile benthic species, the evaluation of risks on a point-by-point basis is the appropriate spatial scale of risk analysis. Thus, we also do not agree with LWG's contention that the TZW data are not representative of the potential for unacceptable risks on a larger spatial scale. Rewrite this section to take into account the possibility that the spatial extent of unacceptable risks to benthic infauna are likely underestimated.	Issue
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	As resolved in the EPA-LWG non-directed comments meeting (LWG 2010b), no further analysis of lesion data is needed for the Draft Final BERA.	jmk-cdm smith
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47	LWG Comment Response	Reviewer
	Please see response to comment 27.	jmk-cdm smith
48		
	No changes were made because the requested analysis is pertinent to the RI discussion of nature and extent of contamination rather than risks.	jmk-cdm smith
49		
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51	LWG Comment Response	Reviewer
52	The range of fish target size lengths and criteria for composite tissue samples were added to the text in Section 4.	jmk-cdm smith
	Please see response to comment 20. Additionally, presentation of the number of samples exceeding thresholds is not appropriate in all cases because potentially unacceptable risks are determined on an exposure-area basis rather than a sample-specific basis (see response to comment 17).	jmk-cdm smith
53		
54	Tables have been added to Section 5 accounting for the COIs for which no screening values are available. These are also presented in the individual risk characterization sections for benthic invertebrates, fish, wildlife, amphibians, and aquatic plants.	jmk-cdm smith
55		
56	LWG Comment Response	Reviewer
	In the 9-9-10 LWG-EPA meeting to resolve EPA-directed changes, EPA indicated erroneously that there is an AWQC value for the protection of aquatic life, though based on protection of human health. Based on this assertion, the LWG agreed to present both an ecologically relevant screening value and the EPA-directed value based on protection of human health but to screen on the lower EPA-directed human health criterion. LWG agreed to this because changing the screening value to EPA's directed value does not change the results of the screen (2,3,7,8-TCDD does not screen in as a surface water COPC at a screening value of either 10 or 100 pg/L).	jmk-cdm smith
57	No change was made to the text. Per agreement with EPA (resolution of non-directed comments(LWG 2010b)), a species-specific screen is acceptable. The suggested approach would not change the risk conclusions for any receptor-COPC pair but would require additional tables and text ultimately making the document more difficult to understand.	jmk-cdm smith
58		
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60	LWG Comment Response	Reviewer
	Please see response to comments 17 and 43. Additional discussion of the relationship between organism-level measurement endpoints and population-level assessment endpoints was added to a text-box in Section 3.0	jmk-cdm smith
61		
62		
63	LWG Comment Response	Reviewer
	No change has been made in response to this comment. The information presented in this comment is incorrect. The maximum TBT value in surface water (presented in Table 5-4 of Attachment 5) is 0.014 ug/L, which is a detection limit; the maximum detected concentration of TBT in surface water is 0.0035 ug/L. Because both values are less than the chronic AWQC of 0.072 ug/L, TBT was not retained as a COPC in surface water. (However, monobutyltin was retained as a COPC.) Butyltins were not analyzed in TZW; there are no values to compare with screening thresholds. TBT was not retained as a COPC in TZW.	jmk-cdm smith
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66	LWG Comment Response	Reviewer
	Regarding TZW, see response to comments 41 and 99.	jmk-cdm smith
67		

	addressed
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47	Comment Status
	addressed
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	not addressed
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51	Comment Status
52	addressed
	not addressed
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56	Comment Status
	addressed
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	addressed
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60	Comment Status
	partially addressed
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63	Comment Status
	not addressed
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66	Comment Status
	partially addressed
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	J
45	The table is unchanged but fish exposure to PAHs is described in Section 7.5.
46	
47	CDM Review Comment (page numbers refer to July 2011 clean copy)
48	Risks to fish are evaluated in Section 7. The new Table 7-11 presents lengths and weights of fish from the study area and upriver. This is discussed in section 7.1.5.2.2, which compares study area tissue to upriver data, and in Section 8.1.5.1.3.
49	
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51	CDM Review Comment (page numbers refer to July 2011 clean copy)
52	Fish lengths were added to Table 4-3; footnote a discusses gender; Lengths and gender are discussed on pages 88 and 89.
53	Tables 5-1 through 5-4 in original document have become 5-1, 5-4, 5-7, and 5-10. The requested revisions were not incorporated.
54	
55	These are presented by receptor group in Tables 5-3, 5-6, 5-9, and 5-12. Uncertainties for BMI are discussed in Section 6.6.5.3, 6.4.5.4, and 6.7. Related Tables include 6-6, 6-28, 6-35, and 6-42.
56	CDM Review Comment (page numbers refer to July 2011 clean copy)
57	For surface water, changes were made to Section 6.1 and Tables 6-2 and 6-4 of Attachment 5. No revisions are needed for Table 6-5 and 6-6 (assuming that the maximum concentratins are correct). For TZW, changes were made to Table 7-2 and 7-4 of Attachment 5. The associated text was not revised. Table 6-4 compares surface water maximum concentrations to 10 pg/L for dioxin, so it was not selected as a COPC. Thus, revisions were not needed in Section 5.1 (assuming correct maximum detects).
58	Requested revisions to Section 5.3 have not been incorporated.
59	
60	CDM Review Comment (page numbers refer to July 2011 clean copy)
61	The referenced text box was removed. A text box about uncertainties associated with population and organism level effects was added to Section 3.0 (page 61) but the content does not appear to meet the intent of the comment.
62	
63	CDM Review Comment (page numbers refer to July 2011 clean copy)
64	Table 6-4 of the SLERA/Refined screen compares a maximum concentration in surface water (DL of 0.014 ug/L) to AWQC (0.072 ug/L), so it is not retained for evaluation in the BERA. The BERA does not identify tributyltin as a COPC for TZW and does not compare a detected concentration or detection limit to the AWQC, since the SLERA/Refined screen did not identify tributyltin as a TZW COI in Table 7-1 of Attachment 5.
65	
66	CDM Review Comment (page numbers refer to July 2011 clean copy)
67	The text box has been removed and replaced by Section 6.6.3.3, which discusses exposure uncertainties associated with TZW, However, it concludes with stating that risks associated with exposure to porewater "is highly questionable."

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47	New EPA Comment	New Comment Code
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51	New EPA Comment	New Comment Code
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63	New EPA Comment	New Comment Code
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66	New EPA Comment	New Comment Code
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	A	B	C	D
	Specific Comment	96	6.7	p. 213
68				
69				
70	Comment			Page
71	Type	No.	Section	Line(s)
72	Specific	97	6.7.2	p. 216
73	Comment			
74				
75				
76				
77				
78				
79	Specific	100	6.7	6.7 p.
80	Comment			213
81				Lines 20-
82				21
83				
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87	Comment Type	No.	Section	Page Line(s)
	Specific Comment	103	7	p. 237
88				
89	Specific Comment	104	7	p. 238
	Specific Comment	105	7	pp. 235 -236
90				
	Specific Comment	106	7.1.1	p. 242
91				
92	Specific Comment	107	7.1.2.1	p. 245
	Specific Comment	108	7.1.2.2	
93				
94	Specific Comment	109	7.3.1	p. 244
95				
96	Comment Type	No.	Section	Page Line(s)
	Specific Comment	110	7, Attach. 9	pp. 248-9
97				
	Specific Comment	111	7.1.3	pp. 249-50
98				
99				
100	Comment Type	No.	Section	Page Line(s)

	E	F
68	The draft BERA states that " <i>the measurement endpoints are determined at the organism level</i> " and " <i>conclusions about unacceptable risk to populations and communities can be drawn only by extrapolating from potential effects in individual organisms.</i> " Risk was measured by using test populations (e.g., laboratory test populations of <i>Hyaella</i> and <i>Chironomus</i>) to infer risk to site populations. Effects on these populations are used to infer risk about site communities (e.g., changes in growth, mortality has been linked extensively to changes in benthic community structure - EPA 2000). For example, changes in growth in bioassay tests have been linked to changes in community structure and diversity. Organisms that do not grow properly cannot emerge from sediment to reproduce. Ability to colonize new substrate is also affected. For the benthic invertebrate tissue residue lines of evidence, effects and risk were measured on tissue composites, not individuals. The only way to truly evaluate changes in community structure associated with environmental degradation is to evaluate alterations in benthic community structure in the field. Since this evaluation was not done on the site, it must be assumed that changes in endpoints such as growth and mortality result in benthic community effects in the field. It is further stated that " <i>localized TRV exceedances do not indicate population- or community-level risks</i> ". This statement is not accurate. Rather, single exceedances represent population-level effects and degradation of the benthic community in that localized area.	Issue
69		
70	EPA Original Comment	Original Code
71		
72	Weight of Evidence: It is determined here that the predictive models represent a stronger line of	
73	evidence than empirical data because " <i>the historical distribution of chemicals in sediment is</i>	
74	<i>limited, and sediment samples do not integrate well over a wide area</i> ". Mapping and the food	
75	web model were then used to predict where exceedances would occur, and to identify potential	
76	risk areas (PBRAs). This is not an appropriate use of the weight of evidence approach, as the	
77	models do not incorporate empirical results from the site.	
78	Overlay each line of evidence on a map.	
79	The Benthic Risk Conclusions and Uncertainty section states that measurement endpoints for	Revise
80	benthic risk are determined at the organism level. For surface water and TZW samples compared	
81	to EPA water quality criteria, this statement is not correct. EPA water quality criteria are	
82	designed to be protective of 95% of aquatic genera (Stephan et al. 1985, p. 2). This is a taxa	
83	richness measure, which is a community-level endpoint, not an organism-level endpoint.	
84	Correct all draft BERA discussions of water quality criteria as an organism-level endpoint (such	
85	as that in Section 6.7.1, p. 214) to reflect the fact that they are a community-level endpoint.	
86		
87	EPA Original Comment	Original Code
	Revise the RI Report to reflect the fact that tissue concentrations are based on composite fish tissue samples, not individuals. The RI Report should further note that TRVs are based on laboratory populations measuring effects. The language here about conservatism is unsupported unless population attributes will be measured in the future.	Clarify
88		
89	The report does not mention here the high degree of uncertainty associated with "information about feeding rates, foraging areas, prey home ranges, and diets" for fish species. The revised BERA should discuss these uncertainties as they relate to the strength of the line of evidence as presented here.	Clarify
	The following parameters are very important variables for the dietary exposure levels: feeding rates, foraging areas, prey home ranges, and diet composition for each species. Was a sensitivity analysis done for the key variables? How were the key variables or ranges decided upon? Provide some ranges for these values to help understand how sensitive these parameters were to the calculations.	Clarify
90		
	Per the problem formulation, risks to carp from bioaccumulated chemicals in their tissues must be evaluated. This analysis does not appear to have been performed. Also, uncertainties of risks to carp from bioaccumulated dioxin-like chemicals in their tissues have not been discussed. If dioxin-like chemicals did not screen in, this should also be discussed in the uncertainty analysis. Both of these analyses were called for in the problem formulation, and must be performed.	Clarify
91		
92	Assessment Based on Individual Samples text box: Information presented in this box is misleading. Attributes to do a population-level risk assessment were not made, including concentration determinations by age class, individual concentration measurements, fecundity, etc. The BERA should be revised accordingly.	Issue
	Predicted tissue concentrations for sculpin were based on the food web model. As part of the uncertainty analysis, use BSAFs and BSARs to validate the model predictions for sculpin. The food web model is a site-wide model, predicting average tissue concentrations for this species. It is unclear if these predictions produce accurate estimates of risk to this species.	Issue
93		
94	Include the carp home range of 3 river miles used in the exposure assumptions in Table 7-3.	Clarify
95		
96	EPA Original Comment	Original Code
	Several of the fish tissue TRVs are not in agreement with the values given to the LWG by EPA. The antimony LOER is correct in the table, but should have been divided by the default acute-chronic ratio to yield the tissue TRV for the BERA. The lowest value fish tissue TRV for bis(2-ethylhexyl)phthalate is 1.6 mg/kg. As discussed in more detail in an Attachment 9 comment, the 5th and 10th percentile TRVs for cadmium, mercury, and total DDX do not appear to be correct. The 10th percentile total PCB fish tissue TRV also is not correct. Correct the TRVs for these chemicals, and use the correct TRVs to recalculate risks for fish species in the BERA.	
97		
98	Describe in more detail the use of the 5th percentile fish tissue whole body TRVs for juvenile Chinook salmon and Pacific lamprey ammocoetes in the BERA, as opposed to the 10th percentile TRVs used for the other fish species.	Clarify
99		
100	EPA Original Comment	Original Code

	G	H
	Additional discussion of the relationship between organism-level measurement endpoints and population-level assessment endpoints was added to a text-box in Section 3.0.	jmk-cdm smith
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71	LWG Comment Response	Reviewer
72	The empirical data have been included in a weight-of-evidence approach for the benthic LOEs.	jmk-cdm smith
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79	Text has been revised to reflect EPA's comment.	jmk-cdm smith
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87	LWG Comment Response	Reviewer
	The specific text that EPA is referring to is not clear because page 236 presents Figure 7-2 and does not discuss conservatism. The fish tissue-residue LOE was revised throughout to note that tissue concentrations are based on composite samples and that TRVs are based on laboratory populations. An expanded discussion of the relationship between organism measurement endpoints and population-level assessment endpoints was added to a text box in Section 3.0.	jmk-cdm smith
88	Uncertainties associated with these exposure factors are presented in Section 7.2.5.4. Summaries of these uncertainty analyses were added to the risk characterization and risk conclusions sections for cases where they could affect risk conclusions.	jmk-cdm smith
89	Please see response to comment 104.	jmk-cdm smith
90		
	In the 10-15-2010 meeting between LWG and EPA, EPA agreed that consistent with Table 1 (footnote 6) and Table 4 of the Problem Formulation, carp data need only be evaluated for dioxin like chemicals.	jmk-cdm smith
91		
92	An expanded discussion of the relationship between organism measurement endpoints and population-level assessment endpoints was added to a text box in Section 3.0. Please also see response to comment 17.	jmk-cdm smith
	Several problems exist with the suggestion offered in this comment. First, the BSARs (had we developed them for FWM chemicals) would have simply been based on fitting a regression line through co-located sediment and sculpin tissue data. The LWG has already tested the FWM's performance by comparing its tissue concentration predictions to the empirical tissue concentration data, using the co-located sediment concentration data as the input to the model. EPA's proposal would not "validate" the model because the data were already used to calibrate the model. Also, the idea of using a statistical model to validate a mechanistic model is questionable. The reason the LWG used the FWM is that by prior agreement it was decided that the FWM is a better tool for modeling bioaccumulation of persistent hydrophobic organic chemicals.	jmk-cdm smith
93		
94	See response to comment 106.	jmk-cdm smith
95		
96	LWG Comment Response	Reviewer
	The antimony TRV was revised as requested. Please see response to comment 47. Cadmium - No change was made to the cadmium TRV. Six LOERs differ between the cadmium studies presented in the 11-20-08 TRV table transmittal (LWG 2008)and Attachment 9. All differences were directed by EPA. Four sac-fry studies were added (Shazili 1995; Middaugh et al. 1975; Wright et al. 1985; Rombough and Garside 1982) based on EPA's responses to the 11-20-08 TRV tables (LWG 2008), and two behavior studies were added (Scott et al. 2003; Hollis et al. 2000) based on 1-23-09 EPA direction (EPA 2009). The @Risk output files have been included in Attachment 9 of the Draft Final BERA. DDX - No change was made to the DDX TRV. Two LOERs differ between the DDX studies presented in the 11-20-08 TRV table transmittal and Attachment 9. Both differences were directed by EPA. Two additional studies were added (Berlin et al. 1981; Gakstatter and Weiss 1967) based on 1-23-09 EPA direction (EPA 2009). Note that the 3.0 mg/kg ww LOER for Allison et al. (1964) was included in the 11-20-08 TRV transmittal (LWG 2008)and EPA did not comment on it after that point. PCBs - Five LOERs differ between the 11-20-08 TRV table transmittal and Attachment 9. The two LOERs from Broyles and Noveck (1979) for Chinook salmon and lake trout and one each from Berlin et al. (1981) and Fisher et al. (1994) were included based on 1-23-09 EPA direction (EPA 2009). The LOER from Nebeker et al. (1974) was revised based on EPA's 12-22-08 response (EPA 2008a) to LWGs 11-20-08 revised TRV tables (LWG 2008). Mercury - Subsequent information on the lowest LOER for the Hg TRV was obtained. As agreed in the 10-15-10 LWG-EPA meeting, the TRV derivation was revised to reflect this change. Additionally, two LOERs differ between the mercury studies presented in the 11-20-08 TRV table transmittal (LWG 2008)and Attachment 9. Both differences were directed by EPA. The Webber and Haines (2003) behavior LOER was included based on 1-23-09 EPA direction (EPA 2009). The Heisinger et al. (1979) LOER was revised and was included based on EPA's 12-22-08 response (EPA 2008a) to LWGs 11-20-08 revised TRV tables (LWG 2008). Lindane - See response to comment 205. BEHP - Consistent with EPA's 12-22-08 response (EPA 2008a)to LWGs 11-20-08 revised TRV tables (LWG 2008), no acceptable BEHP TRV was identified.	jmk-cdm smith
97		
	The BERA was revised as requested.	jmk-cdm smith
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100	LWG Comment Response	Reviewer

	partially addressed
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71	Comment Status
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79	not addressed
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87	Comment Status
	partially addressed
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89	addressed
	partially addressed
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	not addressed
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	partially addressed
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	not addressed
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	J
	The first statement has been removed from the revised BERA but the second statement remains. This section now provides a weight of evidence approach used to evaluate risks to BMI. They factors LWG included to look at population risks from organism-level lines of evidence are listed. It does not appear that revisions were made to address the intent of the comment.
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71	CDM Review Comment (page numbers refer to July 2011 clean copy)
72	The referenced statement has been removed from Section 6.7. The lines of evidence appear to be presented in the map series 28a-b and discussed in Section 6.7.2.
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79	Although revisions have been made to this section, the intent of the comment was not addressed. Further, an uncertainty discussion regarding extrapolating from organism to population level effects is provided on page 61.
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87	CDM Review Comment (page numbers refer to July 2011 clean copy)
	Text in Section 7 has been revised to note that the results are based on composite tissue samples (p 317, 321, 322) . Text was revised (p 318 for example) to indicate TRVs are based on laboratory populations. The statement about conservatism was removed from this referenced section; however, similar statements remain throughout the document.
88	
89	This section has been revised to include requested revisions.
	Section 7.2.5.4 and its subsections describes uncertainties regarding prey consumption and ingestion rates. Not all of the variables referenced in the comment are evaluated.
90	
	The statement made about carp in Section 7.1.1 being a surrogate remains, now as footnote 82 in the same Section (now 7.1.2) on page 334.
91	
92	The referenced text box has been removed. A text box about uncertainties regarding organism and population level effects is presented in Section 3 (page 61); however, the attributes identified in the comment do not appear to be discussed.
	The section is now 7.1.3.2. Although the text has been revised, it does not appear as though changes were made to address the comment.
93	
94	The table was removed and carp no longer appear to be evaluated in this section.
95	
96	CDM Review Comment (page numbers refer to July 2011 clean copy)
	LWG presents fish tissue TRVs in Attachment 9 (unlabeled table -- pdf page 122 of 143) and in it is a revised antimony LOAEL to now be 1.1 mg/kg ww. The 5th percentile concentration of DDX and mercury are 0.77 and 0.45 mg/kg ww, respectively, and the 10th percentile mercury concentration has been revised to be 0.53 mg/kg ww. The others referenced in this comment are either unchanged (PCBs, cadmium) or are not presented (bis(2-ethylhexyl phthalate)). Table 7-5 in the BERA text has been revised to reflect that attachment revisions. Outstanding need is to independently ID EPA provided fish TRV and compare to those provided in these two places of the document.
97	
	The text was revised in this section (now 7.1.4). No revisions were made to Attachment 9.
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100	CDM Review Comment (page numbers refer to July 2011 clean copy)

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71	New EPA Comment	New Comment Code
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87	New EPA Comment	New Comment Code
88	The introduction has been substantially revised. These issues seem to have addressed, although the overall tone of conservatism remains.	
89	No substantial additional discussion was found.	
90	The citations for the sources of the variables are provided, but no sensitivity analysis was performed.	
91	Risks to carp were only considered for the dioxin-like chemicals, which were screened out by the refined screen. No other discussion of carp was found.	
92	This text box was removed.	
93	No revision or additions to address this comment were found.	
94	Risks to carp are not addressed at this level.	
95		
96	New EPA Comment	New Comment Code
97	The antimony LOER is now divided by the default acute-chronic ratio to yield the tissue TRV for the BERA. For bis(2-ethylhexyl)phthalate a NOAEL of >9.6 mg/kg ww was used; no LOAEL was estimated. TRVs for cadmium are not changed, mercury increased, and total DDX NOAEL increased slightly; no change in LOAEL. The 10th percentile total PCB fish tissue TRV NOAEL decreased very slightly; LOAEL unchanged.	
98	An additional paragraph was added.	
99		
100	New EPA Comment	New Comment Code

	A	B	C	D
101	Specific Comment	112	7.1.3	p. 244 Table 7-5
102	Specific Comment	113	7.1.3	p. 251
103	Specific Comment	114	7.1.4	pp. 251 - 252
104	Specific Comment	115	7.1.4.3.1	p. 260
105	Specific Comment	116	7.1.4.3.2	p. 263
106	Specific Comment	117	7.1.4.3.2	p. 265
107	Specific Comment	118	7.1.4.3.3	p. 265
108				
109	Comment Type	No.	Section	Page Line(s)
110	Specific Comment	119	7.1.4.4	pp. 267-269, Table 7-13
111	Specific Comment	120	7.1.4.5	p. 270
112	Specific Comment	121	7.1.3	p. 249
113	Specific Comment	122	7.1.4.2.1	p. 255, Table 7-8
114	Specific Comment	123	7.1.4.2.2	Table 7-9
115				
116	Comment Type	No.	Section	Page Line(s)
117	Specific Comment	124	7.1.4.2.2	Table 7-10
118	Specific Comment	125	7.1.2.2	p. 242-3, Table 7-4; also Att. 4, Table 4-10
119	Specific Comment	126	7.1.4.3.1	pp. 257-8, Figures 7-3 to 7-5
120	Specific Comment	127	7.1.4.3.2	pp. 260-61, Figures 7- 7,7-8
121				
122	Comment Type	No.	Section	Page Line(s)

	E	F
101	For the final version of this document, LWG made some changes to the fish tissue DDX raw data used that changed the previously derived DDX tissue TRVs. LWG took advantage of the impact that changing a low residue-effect concentration has on the derived TRV. For example, for fish, EPA recommended they use aLOERof 1.1 mg/kg from the Allison etal. (1963) study, in which a range of residues were reported. Since tissue concentrations varied during the study, there is no way to know at what tissue concentration the toxicity effect threshold was exceeded. The conservative approach is to take the lowest number in the range to represent the residue causing an effect. This approach was used in the previous version of the TRV derivation. The least conservative approach is to take the highest concentration at the time of an effect. LWG used the least conservative approach by selecting the highest residue in the time frame in which mortality became significant. By switching to this higher concentration (3.0 mg/kg from 1.1 mg/kg, see page 14 in Attachment 9), the tissue TRV increased significantly (to 1.6 mg/kg ww) from the one originally calculated (0.68 mg/kg). Given that the endpoint is mortality, which is a severe endpoint, the lower tissue residue should be selected from this paper. Another approach is to take the median concentration to represent the range of residues experienced by the fish (1.8 mg/kg). This approach would also be better than using the highest value in the range. Use the original tissue TRV derived for DDX in fish.	Clarify
102	The uncertainties presented in Table 7-6 discuss bias in one direction only. Either present bias in both directions, or delete this table.	Issue
103	In Table 7-7, present the HQs for each COPC and receptor.	Clarify
104	Tissue Data from the Downstream and Downtown Reaches: Data from downstream of the study area exceed TRVs and it was inappropriate not to include these samples in the risk assessment. Since these samples were not carried through the risk screening process, it is impossible to see the COPCs that would have been identified. The "CDF approach" (Figures 7-3, 7-4 and 7-5) does not represent a risk screening. One example includes sculpin exceedances of copper at 3.1 mg/kg (east bank, 3rd highest in the river).	Clarify
105	The RI Report should note that the fish collected from the upriver reach were significantly larger than the fish collected from the harbor. This point should be taken into account as part of this discussion.	Clarify
106	EPA acknowledges that there are regional sources of mercury in the Willamette basin. However, the draft BERA must still evaluate the effect from local sources. Elevated levels of mercury within the site may indicate the presence of local sources.	Clarify
107	In addition to averages, also consider the range and distribution of the data in this evaluation.	
108		
109	EPA Original Comment	Original Code
110	The information regarding the uncertainty of the TRVs is misleading. The species sensitivity distribution approach results in an appropriately conservative TRV protective of the majority of receptors. The BERA should be revised accordingly.	Revise
111	In addition to black crappie and brown bullhead, also perform the evaluation presented in this section for carp.	Revise
112	The selection of the 5th and 10th percentile for protection of threatened and endangered and populations, respectively, is justifiable and should be supported in the BERA text.	Revise
113	In this table, present individual composite risk, not using at 95% UCL concentration - this is only shown in Attachment 12. This table should be similar to Table 7-10 for smallmouth bass. Chemicals that screen in on a individual composite basis should be carried forward into the risk characterization. Present maps on a composite sample-by-sample basis for chemicals that screen in. HQs for carp would be significantly higher for Total PCBs. Large home range fish such as largescale sucker, peamouth and pacific lamprey ammocoetes had the following changes from the SLERA and refined screen: Chromium (2.77 mg/kg), BEHP (3 mg/kg), 4,4'-DDD (0.15 mg/kg) and Total DDX (0.67 mg/kg) were all dropped in the final risk characterization step. Lamprey ammocoetes: Diethyl phthalate, and 4,4'-DDD (max detect 0.0547 mg/kg) were all dropped and not discussed here. These were due to uncertainties in the TRV, high detection limits, and changes in the TRV, respectively.	Revise
114	Several COPCs are dropped from the SLERA and refined screening, including BEHP, 4,4'-DDD, 4,4'-DDT, and beta-HCH. BEHP was dropped because of "uncertainty with the TRV (instead, discuss in Uncertainty section), even though there were significant exceedances of both the TRV used in the SLERA and refined screen (0.39 mg/kg) and the final TRV (9.6 mg/kg) (max detect was 28 mg/kg). 4,4'-DDD was dropped because the TRV went from 0.054 mg/kg to 1.6 mg/kg total DDX TRV (highest detect 4,4'-DDD was 0.305 mg/kg), and 4,4'-DDT was dropped because the TRV went from 1.7 mg/kg to 1.6 mg/kg Total DDX TRV (highest detect 4,4'-DDT 1.7 mg/kg). These congeners should have been carried forward, not just total DDX. Beta-HCH was dropped because TRV went from 0.0049 mg/kg to 0.20 mg/kg (highest detect was 0.0062 mg/kg). This process drops localized effects from the risk characterization process. Maps presented on a composite sample-by sample basis are only for the refined list, which is misleading.	Issue
115		
116	EPA Original Comment	Original Code
117	This table should not drop BEHP, which had 2 exceedances of the TRV at 87 mg/kg and 32 mg/kg. Table 7-7 (p. 254) also show these exceedances. Therefore, it is unclear why Table 7-10 does not show the BEHP as "area specific tissue 10th percentile LOAEL HQ". This COPC should not be dropped due to "uncertainty in the TRV." This is not appropriate. Re-evaluate antimony risks using the correct BERA TRV of 1.1 mg/kg. Total DDx and 4,4'-DDD were also dropped in this step because the TRV went from 720 mg/kg to 1,600 mg/kg from the screening steps to final selected TRVs, a change that was not approved by EPA. Retain the original BERA DDx and 4,4'-DDD TRVs.	Issue
118	This table indicates that the mechanistic model was used to predict tissue concentrations of beta-HCH in sculpin. However, Table 4-10 of Attachment 4 does not report predicted concentrations for beta-HCH. It only lists predicted sculpin tissue concentrations for total PCBs and total DDX.	Issue
119	Given the high site fidelity of sculpin (0.1-mile range according to this assessment), you cannot characterize fish tissue residues in the 3.5-mile downtown reach and the 1.9-mile downstream reach that bracket the study area with only 2 sampling locations in each reach. Approximately 40 sites were used to characterize the 9.9-mile study area. More locations outside the study area should be sampled before comparing these areas to the study area.	Issue
120	The sparse amount of fish tissue data is insufficient to characterize the 13.1-mile upriver reach. Data for a total of 13 fish and 4 lamprey ammocoetes collected over 4 years is presented. It is misleading to say that lamprey ammocoetes collected from the upstream reach have higher mercury and copper concentrations than those in the study area when only 4 individuals from the upstream reach were used for comparison. The error bars on Figures 7-7 and 7-8 suggest that there is high variability with these analyses, and the standard deviation should be reported for these concentrations. More locations outside the study area should be sampled before comparing these areas to the study area.	Issue
121		
122	EPA Original Comment	Original Code

	G	H
	No change to the DDx TRV was made. Allison et al. (1964) report results from two experiments conducted in parallel over 3 years—a water exposure and a dietary exposure study. In the water exposure, the lowest LOAEL could not be precisely determined because tissue residues were not measured at the time point where adverse effects were observed. Because of this, the associated LOAEL tissue concentration is somewhere between what was measured at a prior and later time point. In the parallel dietary study, tissue concentrations where adverse effects occurred were clearly higher than in the water exposure study. Therefore, the LWG contends that it is appropriate to select the higher concentration measured at the later time-point from the water study as the appropriate lowest LOAEL from this study. The geomean of the two LOAELs reported in this study would result in a higher LOAEL than that used in the SSD. Regarding selection offish tissue TRVs, please see response to comments 47 and 110.	jmk-cdm smith
101	Additional information on uncertainties associated with the selected TRVs was added to this section but no changes were made to this table because it is specific to those PCBs TRVs that were included despite their high degree of uncertainty.	jmk-cdm smith
102	Although the LWG generally disagrees that HQs should be added to summary tables, HQs were added to Table 7-7 because doing so eliminated the need to present sample-specific HQs in Attachment 12. Sample-specific HQs were already reported for most receptors, so eliminating tissue-residue TRVs from Attachment 12 makes the document more concise. Please also see response to comment 20.	jmk-cdm smith
103	Discussion of downstream data relative to TRVs in Section 7.1.5.2 was expanded. As resolved in the EPA-LWG non-directed comments meeting (LWG 2010b), the CDF approach provides a good and proper means of presenting downstream data relative to the Study Area data. The LWG agrees to discuss the downstream data relative to TRVs in the risk characterization and uncertainties associated with downstream data (e.g., number of samples).	jmk-cdm smith
104	Please see response to comment 27.	jmk-cdm smith
105	Please see response to comment 27. Note that because the fish mercury tissue-residue TRV was changed (as agreed to between EPA and LWG in the resolution of non-directed comments (LWG 2010b)), mercury fish-tissue HQs are < 1. Therefore, comparison for background mercury was moved to Section 8.1.5.1.3 as it pertains to risk to bald eagle.	jmk-cdm smith
106	Note this is now in Section 8. Please see response to comment 117. The range and distribution of the data are now discussed.	jmk-cdm smith
107		
108		
109	LWG Comment Response	Reviewer
	While the LWG agrees that the SSD approach for deriving TRVs results in appropriately conservative TRVs protective of the majority of receptors, several of the TRVs summarized in Table 7-13 have significant uncertainties not specifically related to the SSD methodology. An expanded discussion of TRV uncertainties is included in Section 7.1.3 and summarized in Table 7-5. The uncertainties presented in Table 7-13 are consistent with the uncertainties raised in these earlier sections of the document.	jmk-cdm smith
110	See response to comment 106.	jmk-cdm smith
111	The BERA was revised as requested.	jmk-cdm smith
112	Regarding the exposure areas and EPC calculation for receptor species, please see response to comment 17. As resolved in the LWG-EPA non-directed comments meeting, carp was evaluated only for dioxin-like chemicals; total PCBs was not included. (Please see response to comment 106.) Chromium, BEHP, 4,4'-DDD, and total DDx were all retained as COPCs and therefore by definition were not dropped from the SLERA and refined screen. COIs were identified as COPCs in the SLERA and refined screen based on EPA directed screening-level TRVs. A different TRV (based on the agreed approach between LWG and EPA for developing a 5 th and 10 th percentile LOAEL) was used in the BERA and some chemicals (such as chromium) did not exceed the BERA TRVs. BEHP was identified as a COPC based on the SLERA and refined screen; however, because only a NOAEL could be identified, baseline risks could not be evaluated. (Please also see response to comment 124.) 4,4'-DDD was evaluated in the BERA as total DDx, not as an individual metabolite. Diethyl phthalate was not a BERA COPC because all results were non-detects and, therefore, it was dropped in the refined screen. Maps of individual tissue-residue samples exceeding TRVs were added for largescale sucker, peamouth, and lamprey along with those already provided in the draft BERA for small-home-range species.	jmk-cdm smith
113	No change was made for any chemical listed except BEHP. The information presented in the comment is incorrect. The chemicals listed (BEHP, 4,4'-DDD, 4,4'-DDT, and beta-HCH) were all retained as COPCs and, by definition, were not dropped from the SLERA and refined screen. BEHP was evaluated as part of the risk characterization, identified as a chemical with "potentially unacceptable risks" due to the uncertainty of the TRV. Revised tissue TRVs were developed per agreement with EPA (screening level TRVs were often not based on tissue data, but were based on modeled screening-level values using BCFs and AWQC) and are presented in Attachment 9. Because tissue concentrations for 4,4'-DDD and beta-HCH do not exceed these EPA-agreed-upon tissue TRVs (see Attachment 12), these contaminants were not carried forward as contaminants potentially posing risk. 4,4'-DDT was not evaluated as an individual COPC; instead, it was evaluated as a component of total DDx, which is consistent with EPA direction. In an attachment to an e-mail dated 9-12-08 (EPA 2008b), EPA stated that a total DDx approach, rather than individual DDT congener approach, should be used.	jmk-cdm smith
114		
115		
116	LWG Comment Response	Reviewer
	BEHP was identified as posing potentially unacceptable risks in the Draft Final. The LWG disagrees that BEHP should be included in Table 7-10 because this table presents LOAEL HQs and no BEHP LOAEL TRV was identified (only an unbounded NOAEL TRV was identified). Antimony was re-evaluated using the revised TRV as requested. In the 10-15-10 meeting with the LWG, EPA confirmed that a total DDx approach, rather than individual DDT congener approach, should be used; therefore, risks from 4,4'-DDD were not specifically assessed. Regarding the final tissue TRVs, please see response to comments 47, 110, and 112. Regarding screening of DDTs, see response to comment 123.	jmk-cdm smith
117	Beta-HCH was added to Attachment 4.	jmk-cdm smith
118	Please see response to comment 115.	jmk-cdm smith
119	Please see response to comment 27.	jmk-cdm smith
120		
121		
122	LWG Comment Response	Reviewer

	not addressed
101	not addressed
102	addressed
103	not addressed
104	addressed
105	partially addressed
106	not addressed
107	
108	
109	Comment Status
	not addressed
110	not addressed
111	addressed
112	partially addressed
113	partially addressed
114	
115	
116	Comment Status
	partially addressed
117	addressed
118	not addressed
119	partially addressed
120	
121	
122	Comment Status

	J
	The value of 1.6 mg/kg remains unchanged in Table 7-5 for the DDx 10th percentile LOAEL. The value for the 5th percentile was modified slightly from 0.76 to 0.77 mg/kg. The table refers the reader to discussion about DDX following the table; however, the rationale for not changing the value as requested in the comment is found in the paragraph before the table.
101	
	The table remains and no related changes were made.
102	
	Table 7-7 was revised to include HQs among other information (# samples, # samples with HQ>1).
103	
	The text in this section (7.1.5.2.1) has been revised but the data included and evaluated remains unchanged.
104	
	The new Table 7-11 presents lengths and weights of fish from the study area and upriver. This is discussed in this text section (now 7.1.5.2.2) and in Section 8.1.5.1.3.
105	
	This statement/discussion has been removed from this section (now 7.1.5.2.2) but is now in Section 8.1.5.1.3).
106	
	This section was removed. The information was moved to Section 8.1.5.1.3 but the range/distribution of mercury concentrations is not evaluated. The context is now different--now is associated with discussion about risks to eagles.
107	
108	
109	CDM Review Comment (page numbers refer to July 2011 clean copy)
	The referenced table has been removed; however, these uncertainties are provided in Table 7-5 of the revised document. The process for selecting TRVs referenced in these tables (with the uncertainties) are provided in Section 7.1.4. Uncertainties regarding TRV selection are further discussed throughout Section 7.1.5.
110	
	Carp has not been added (now Section 7.1.5.5) to this section (pages 354-355).
111	
	This section (now 7.1.4) described the use of the 5th percentile for T&E species (p. 328). Section 7.2.4 indicates that threatened species were evaluated at the individual level, using the NOAEL.
112	
	Following discussion with Burt regarding TRVs in the BERA group meeting held in Portland, Burt subsequently reviewed this comment in detail and indicated that associated text edits were needed.
113	
	The table was removed. BEHP is discussed in the text. No revisions were made relative to DDD, DDT, Beta-HCH in the carp evaluation. Figures were revised for sculpin tissue.
114	
115	
116	CDM Review Comment (page numbers refer to July 2011 clean copy)
	This table is now 7-9. Antimony was added to the table. BEHP is discussed in the associated text section (but not added to the table). DDX and DDT were not added to the table or text discussion (Section 7.1.5.1.2).
117	
	Beta-HCH was added to Table 4-10 of Attachment 4.
118	
	The figures have been reordered but appear to be unchanged. The text was expanded but additional samples were not included or discussed. The text notes that inclusion of additional downstream samples would result in greater extent of copper exceeding TRVs but that it is an uncertainty.
119	
	The mercury figures have been removed. The number of samples and number of fish per composite are discussed in this section (now 7.1.5.2.2) and presented on Table 7-11, although the fish/sample numbers do not match those in the comment. The text does not indicate that any additional samples were collected.
120	
121	
122	CDM Review Comment (page numbers refer to July 2011 clean copy)

	K	L
	The TRV of 1.6 mg/kg was still used.	
101		
	Only minor changes were noted.	
102		
	The table presents the HQs for only those pairs that screened in at this point.	
103		
	This section was substantially revised and notes that no new COPCs would be added by the data from the other reaches, as well as that the range of areas affected by copper would be extended if the other data were considered.	
104	Overall the conclusions did not change markedly.	
	A table and discussion of the fish size metrics was added, and while it was noted that differences could affect the bioaccumulation of the persistent substances, this information was not included in the comparisons of concentrations among the areas.	
105		
	The mercury discussion was removed.	
106		
	Additions made.	
107		
108		
109	New EPA Comment	New Comment Code
	The text has been somewhat revised and indicates that the uncertainties may be either more or less protective, but the discussion still highlights primarily the unreliability of the TRVs.	
110		
	As not above, carp were eliminated by the screening and were not included in this section.	
111		
	The text is careful to not be too accepting of any of the TRVs, without actually stating they were totally over-protective.	
112		
	The individual composites exceeding the TRVs was shown in Table 7-7, which seems to accomplish what this suggestion requests, without needing to change Table 7.8. For the large scale sucker and lamprey ammocoetes, no changes noted.	
113		
	BEHP and beta-HCH were carried through Step 1 in BERA(Table 7-7). DDD and DDT were not individually considered, but the text does not discuss why.	
114		
115		
116	New EPA Comment	New Comment Code
	BEHP, DDX and 4,4'-DDT were not retained.	
117		
	Beta-HCH was added to Table 4-10.	
118		
119		
	The revised text notes the limited samples and the disparity in number of samples, stating that these data don't support a robust comparison among the areas. The comparisons are done anyway, however.	
120		
121		
122	New EPA Comment	New Comment Code

	A	B	C	D
	Specific Comment	128	7.2; 8.1	Multiple pages and line numbers
123				
	Specific Comment	129	7.2.2.2	p. 227 ff
124				
125	Specific Comment	130	7.2.4.1	p. 287
126				
127	Comment Type	No.	Section	Page Line(s)
	Specific Comment	131	7.3	p. 315
128				
	Specific Comment	132	7.3.2.1	p. 318
129				
	Specific Comment	133	7.3.3.3, 7.3.3.3.1, and 7.3.3.3.2	pp. 323-325
130				
	Specific Comment	134	7.3.3.3.1	p. 319
131				
	Specific Comment	135	7.3.4	p. 325
132				
133				
134	Comment Type	No.	Section	Page Line(s)
	Specific Comment	136	7.4.4	p. 339
135				
	Specific Comment	137	7.5	p. 340, paragraph 4, last sentence
136				
	Specific Comment	138	7.6	pp. 341, 346
137				
	Specific Comment	139	7.6.1	p. 347
138				
	Specific Comment	140	7.6.2	pp. 347, 348,353-362.
139				
	Specific Comment	141	7.6.2	p. 350
140				
	Specific Comment	142	7.6.3	pp. 346-7
141				
	Specific Comment	143	7.6.3	Table 7-40
142				
143				

	E	F
123	There appear to be two technical errors in the calculation of risks to fish and wildlife from ingestion of contaminated diets. 1.) Calculating dietary risks by adding together the two hazard quotients for risks from ingestion of contaminated prey and risks from ingestion of contaminated sediment. Total risks from all components of the diet should be calculated by summing the ingested doses from sediment and contaminated prey ingestion, then calculating a single hazard quotient combining risks from the two dietary fractions. The equation for this was given as Equation 1 on page 40 of the February 15, 2008, Problem Formulation. It appears as though LWG has summed the hazard quotients from the two dietary fractions to obtain total risk, rather than the correct approach of summing the two ingested dose estimates, then calculating a single hazard quotient. EPA does not object to the LWG approach of quantifying risks separately from sediment ingestion and contaminated prey ingestion, as this provides useful information. However, the total dietary risk calculations should be corrected as described earlier in this comment. 2.) In the situation where only one of the two dietary fractions (either sediment or prey) has a hazard quotient > 1, the BERA shows the final HQ as only the HQ from the pathway with HQ > 1, not the sum of both HQs. This is not correct. Total risk is that from the sum of ingested doses from sediment and prey. The LWG approach underestimates total dietary risks. Another problem with the BERA approach is the situation where both sediment and prey ingestion HQs are between 0.5 and 1.0, in which case the BERA drops both dietary fractions and concludes that chemical does not pose a risk. One could have a situation where prey HQ = 0.7 and sediment HQ = 0.7, for example, yielding a total HQ of 1.4 and a chemical of concern. The BERA approach would not identify such a chemical as posing risk to ecological receptors. Dietary ingested doses must be summed before calculating the total dietary HQ, even when both individual components of the diet (sediment and prey) have individual HQs < 1.	Issue
124	The draft BERA creates and applies separate tissue and sediment thresholds to calculate HQs from the exposure data for prey and sediment (Eqs 7-4 and 7-5). While the HQs are added in the final analysis, which is equivalent to Eq. 7-3, it was not clear whether some fish risks were underestimated because they were screened out in the earlier steps of the screening process when the prey and sediment consumption data were not combined. The BERA should clarify this point.	Clarify
125	Step 2 should reference Table 7-17, not Table 7-15.	Revise
126		
127	EPA Original Comment	Original Code
128	It is not appropriate to calculate 95% UCL on water concentrations for comparison to larger home range fish. Even if they are wider ranging, they will still be exposed above chronic or acute TRVs during some time frame. All fish except sculpin were evaluated as 95% UCL on the mean over some exposure area. For all practical purposes, all fish should be evaluated on a sample-by-sample basis. Per the problem formulation, <i>"compare every individual water sample to water TRVs. Consider exceedance of acute or chronic values at any scale a risk (near bottom and integrated) due to lack of sufficient samples to accurately obtain better exposure resolution"</i> . Therefore, the assessment for sculpin, with the addition of the peristaltic samples, should be used to assess risk to all fish. This is presented in the text, but not in Table 7-36, where only 1 mile exposure areas are presented, but see Maps 6-30 through 6-34. There are several widespread exceedances - esp. of DDX and isomers - that support the conclusion that these compounds present a site-wide risk to fish receptors, contrary to the conclusions made in the tissue residue section. While inappropriate, the 95% UCL values used in the risk assessment, along with distribution types, and Pro UCL recommended UCLs are not presented here or in Attachment 4 as stated, making it impossible to see how conclusions would change. While 95% UCLs may be presented somewhere in the document, we have been unable to locate them.	Issue
129	It is not appropriate to drop the results from the peristaltic samples where XAD was collected in the same area. Just because the XAD is based in high resolution does not mean that it represents the same exposure point concentration in terms of spatial and temporal distribution, nor does it represent the same filter size for evaluating total and dissolved metals (XAD was a bigger filter size).	Issue
130	EPA now has a much expanded literature review available on the behavioral effects of copper to fish, including salmonids, than was available to share with LWG during the preparation of the draft BERA. EPA can share the expanded review with all interested parties, including the LWG. Based on our updated literature review, EPA believes that the major uncertainty regarding copper effects on fish behavior, including avoidance responses and the potential to interfere with migration, is the difference in the olfactory threshold concentrations (i.e., the lowest concentrations of copper in water a fish can smell), and the higher threshold concentrations of copper in water required to elicit behavioral responses. The olfactory and behavioral threshold concentrations are not the same. A brief revised discussion of this is warranted in the BERA. It should also be recognized that olfaction is a suborganismal endpoint involving multiple tissues and organs, whereas behavior is an organism-level response to contaminants.	Clarify
131	This section should be revised. The statement that the impairment of olfactory systems in fish due to metals exposure is temporary is misleading. The re-growth of new cells has been shown in the lab following exposure, but only in non-contaminated water.	Issue
132	Section 7.3.4, Risk Characterization: This section should be revised to incorporate the comments on the previous sections. Do not use 95% UCLs on the mean and alternative TRVs should not be used.	Revise
133		
134	EPA Original Comment	Original Code
135	Even though there are no complete studies that link population-level effects to PAH-caused skin lesions in fish, this does not mean that this risk can be ignored. There are plenty of studies linking various skin lesions to fish mortality on individual- and population-level scales. The bulk of this research stems from the aquaculture industry's investigation into the effects of sea lice on salmon populations and other causes of skin lesions in farmed fish. Benthic fish would also be more susceptible to bacterial infections facilitated by skin lesions than pelagic species due to the lower dissolved oxygen concentrations found near the water/substrate interface in many aquatic environments.	Note
136	Considering the lack of a dietary exposure line of evidence for lamprey ammocoetes, the decision to not evaluate lamprey exposure to TZW is inappropriate. Lamprey should be evaluated for exposure to TZW. Note that a variation of this comment was provided previously in EPA's December 23, 2009, initial risk assessment comments.	Issue
137	The discussion on Barnhouse et al. (2009) is misleading and the Bamthouse study is flawed and not representative of the situation in Portland Harbor. Remove the final sentence on page 345; it is inconsistent with EPA policy and direction on risk assessments.	Issue
138	Aluminum, cadmium and lead body burdens are not regulated by fish species. Move these chemicals to the non-regulated category of the table. The maximum cadmium concentration in smallmouth bass using the correct tissue TRV yields a hazard quotient greater than 1. Therefore, add cadmium to the list of chemicals posing potentially unacceptable risk for empirically measured fish tissue chemicals.	Revise
139	Tables 7-39 and 7-40: Revise these tables in accordance with comments on previous sections.	Revise
140	There is no basis for the BERA to conclude that there is no population risk.	Revise
141	Avoid statements declaring that no unacceptable risks exist when HQs are > 1. Note that a variation of this comment was provided previously in EPA's December 23, 2009, initial risk assessment comments.	Issue
142	Almost all of the statements in the Risk Conclusions columns are biased in one direction and fail to consider all sources of potential bias. Whenever an HQ is > 1, the table always states that risk is overestimated. There is uncertainty in both directions at each step in the processes they followed. Either highlight the major uncertainties and direction of bias, if known, for each step, or eliminate this column. This comment also applies to Table 11-2.	Directed Change
143		

	G	H
123	As resolved in the EPA-LWG non-directed comments meeting (LWG 2010b), the TTC and TSC methods are appropriate for use in the BERA because they result in the same HQs as those resulting from Equation 1 of the Problem Formulation, page 40. Regarding part 2 of this comment, in the draft BERA sediment and tissue contributions were summed to derive total HQs based on Steps 1 and 3 of the risk characterization for dietary assessment. In the Draft Final, Step 2 was revised to sum the dietary and sediment HQs. Regarding the concern raised in the 10-15-10 meeting between LWG and EPA on use of the wet-weight conversion of sediment ingestion rates - Sediment ingestion rates were in dw units. Footnote "d" of Table 7-18 expresses the methods used. Specifically, "SIR = FIR x SI. The SIR was calculated as a percent of the FIR on a dw basis. The dw FIR was calculated based on the following equation: $FIR(dw) = FIR(ww) \times (1 - \text{moisture content of diet})$." This method was followed and no errors were made in the calculations.	jmk-cdm smith
124	Those receptor-COPC pairs that screened in or out in Steps 1 and 2 of the dietary risk analysis are presented in Table 7-23 at the beginning of Section 7.2.5.1 (Risk Characterization Results and Uncertainty Evaluation).	jmk-cdm smith
125	The requested change has been made.	jmk-cdm smith
126		
127	LWG Comment Response	Reviewer
128	Regarding calculation of EPCs, please see response to comment 17. Regarding exclusion of peristaltic samples, see response to comment 132. Individual sample scale (Table 7-37), 1-mile exposure area (Table 7-40), and site wide (Table 7-38) HQs are presented in separate tables in the fish surface water risk characterization section. ProUCL-recommended surface water UCLs are included in Attachment 4, Part E on the Surface Water EPCs tab. They are labeled as "sitewide" under the Exposure Scale column.	jmk-cdm smith
129	As agreed in the 10-15-10 EPA-LWG meeting, an uncertainty analysis was conducted to determine the effects of excluding peristaltic samples. Results of this uncertainty analysis are presented in Section 6.5.4.2.2.	jmk-cdm smith
130	This section was updated and incorporated additional information provided by EPA.	jmk-cdm smith
131	This section has been updated to clarify that the ability of olfactory systems to recover from copper exposures depends on the exposure concentration and the duration of the exposure.	jmk-cdm smith
132	Revisions to earlier sections were considered in risk characterization. Regarding use of UCLs, please see response to comment 17.	jmk-cdm smith
133		
134	LWG Comment Response	Reviewer
135	Please see response to comment 63.	jmk-cdm smith
136	Please see response to comment 41.	jmk-cdm smith
137	Discussion of Barnthouse et al. (2009) was removed from the Draft Final. Please also see response to comment 3.	jmk-cdm smith
138	As discussed by Meyer et al. (2005) in <i>Toxicity of Dietborne Metals to Aquatic Organisms</i> , fish regulate non-essential metals as well as essential metals; however, in the Draft Final metals were divided into the categories of inorganic and organic rather than regulated and non-regulated metals. Regarding the cadmium tissue TRV, see response to comments 47 and 110.	jmk-cdm smith
139	Tables were revised consistent with responses to comments 5, 6, and 7.	jmk-cdm smith
140	Please see response to comment 3.	jmk-cdm smith
141	Please see response to comments 5, 6, and 7.	jmk-cdm smith
142	In the 9-9-10 LWG-EPA meeting to resolve EPA-directed changes, the LWG agreed to identify additional instances where uncertainties may result in an underestimation of risk. Additionally, EPA and LWG agreed that because ecological risk assessment relies on conservative assumptions, as stated in ERAGS (EPA 1997), most uncertainties discussed in the BERA are described as resulting in overestimation of HQs and risks. The document has been extensively revised throughout to provide additional discussion of uncertainties and the direction of bias. Regarding the risk conclusions tables, please see response to comment 20.	jmk-cdm smith
143		

	not addressed
123	partially addressed
124	
125	partially addressed
126	
127	Comment Status
	not addressed
128	not addressed
129	addressed
130	partially addressed
131	partially addressed
132	
133	
134	Comment Status
	partially addressed
135	addressed
136	addressed
137	partially addressed
138	partially addressed
139	not addressed
140	partially addressed
141	partially addressed
142	
143	

	J
	Based on the equations 7-4 and 7-5 presented on page 358, LWG appeared to not make the requested change. Two separate equations remain. The site calculations are not clearly presented so it is difficult to confirm, but LWG presents that they conducted two separate calculations. It remains unclear what happens in the following scenario: if sed HQ<1 and food HQ<1 but the sum of both >1 (ie, did LWG use a HQ limit of 0.5 for each term so that sum HQ limit is 1?).
123	
	The calculations are still listed as being completed separately and then summed to identify an HQ. The process is identified on p 318-319, and sect 7.1.5.1. The calculations could not easily be located to verify calculation procedures.
124	
125	The text section has been removed and this table has been removed. The new Table 7-1 provides receptor, exposure scale, and exposure area, but does not retain EPC basis from the former Table 7-17. The former Table 7-1 is now Table 7-2.
126	
127	CDM Review Comment (page numbers refer to July 2011 clean copy)
	The 95% UCLs are still used as EPCs and are provided in Attachment 4E, as noted in LWG's response. The data collected using a peristaltic pump were not re-integrated into the data set if samples were also collected with XAD methods, as noted on page 396.
128	
	The text (now Section 7.3.3.1) seems to infer that the peristaltic data is included and is discussed as an uncertainty. However, Section 7.3.5.1.1 indicates clearly that XAD results were used. The uncertainty analysis conducted was discussed in Section 6.5.5.2.2.
129	
	These sections (now 7.3.4.3, 7.3.4.3.1 and 7.3.4.3.2) have been updated and a new section 7.3.4.3.3 has been added that discusses the protectiveness of AWQC relative to these effects.
130	
	This section is now 7.3.4.3.1 and the statement has been revised to say that "can be" temporary instead of "is" temporary. Literature citations are provided to identify concentrations and time frames of exposure from which fish have recovered.
131	
	This section (now 7.3.5) has been revised but 1) use of alternative TRVs remains throughout and 2) sitewide UCLs are used for HQ calculations for large hime range fish. VOC UCLs or maximum concentrations are used for the sculpin.
132	
133	
134	CDM Review Comment (page numbers refer to July 2011 clean copy)
	This section (now 7.5.4) has been revised but does not seem to meet the intent of the comment.
135	
	This section (now 7.4) presents a discussion of lamprey exposure to TZW.
136	
	This has been removed from Section 7.
137	
	The categorization of COPCs (regulated v not regulated) has been removed from this section. Table 7-45 still states that cadmium is not a COI for any fish species.
138	
	These tables are now 7-45 and 7-46. Revisions were made but they do not incorporate all section comments. For example, TZW was included as a line of evidence but changes were not made based on comment #139 and GRO was not included (as discussed in the newly added footnote).
139	
	Although the text in Section 7.6.3 pertaining to risks associated with exposure to PCBs and DDX has been revised, the meaning remains unaltered. The text now has statements such as "pose potentially unacceptable risk but pose negligible to low risk of ecologically significant adverse effects on Study Area fish populations" or "HQs ≥ 1, and therefore potentially unacceptable risk, occur for total DDx in the surface water, tissue-residue, and TZW LOEs; however, ecologically significant risk to fish populations is not expected."
140	
	This section was revised and many of these references were removed; however, some do remain.
141	
	Table 7-46 replaces Table 7-40 but all uncertainties still state that risk is overestimated. Table 11-2 was removed.
142	
143	

	K	L
123	1) I thought it was agreed that the approaches were mathematically equivalent. The approach used in the BERA did not change. 2) The revised BERA presents the maximum summed combination of prey and sediment HQs. These results are not well presented for the small home range fish, since they are only discussed in the text. In addition, the data in Table 7-29, summarizing the HQs by river mile for smallmouth bass do not match the data in Table 7-2 of Attachment 12, which purports to present the same information. A similar issue was noted for the northern pike minnow data. The HQs in the attachment tables are much greater. I did not check every instance, but this shortcoming (summing of dietary ingested doses before calculating total dietary HQ) seems to have been addressed.	
124	It does not appear that cumulative risks from exposure to multiple substances was ever addressed. This is a major shortcoming of the BERA.	
125	Revised.	
126		
127	New EPA Comment	New Comment Code
128		
129	The data included in the analysis was not changed.	
130	This section was substantially rewritten, and includes some new citations, but it is not clear that the literature view, per se, was used. The distinction between olfactory and behavioral thresholds was made.	
131	This section was revised and seems clear.	
132	The section was revised to summarize the HQs for individual water samples, but the alternative TRVs were used. The UCL concentrations were used to estimate "site-wide" HQs.	
133		
134	New EPA Comment	New Comment Code
135	This whole section was moved, but not substantially changed.	
136	A section was added to specifically address the risks to ammocoetes. The water-only toxicity tests results are used to conclude that the TZW thresholds used for other fish are most likely protective of lamprey.	
137	Barnhouse has been removed.	
138	The table was revised to eliminate the categories. Cadmium was still screened out.	
139	Tables 7-39 and 7-40 were removed and replaced with new tables (Tables 7-45 and 7-46), which provide simple summaries of the results of the five LOEs discussed previously.	
140	The conclusions have been rewritten and is more cautious about using "no risk." However, some substances and exposure routes are stated to have no significant risk to fish populations, even when the HG> 1. Other LOE are stated to pose negligible to low risk, because the TRVs "overpredict risks".	
141	As noted above, the exact phrasing has been revised, but the general tone remains the same. While not stated exactly, it appears that only large HQs can be considered indicative of a real problem.	
142	Table 7-40 was eliminated. The replacement table does not include the same information, but still states only reasons why risks are likely overestimated.	
143		

	A	B	C	D
144	Comment Type	No.	Section	Page Line(s)
	Specific Comment	144	7.6.3	Table 7-40
145				
	Specific Comment	145	7.6.3	Table 7-40
146				
	Specific Comment	146	7.6.3	Table 7-40
147				
	Specific Comment	147	7.6.3	Table 7-40
148				
	Specific Comment	148	7.6.3	pp. 353 ff
149				
150				
151	Comment Type	No.	Section	Page Line(s)
	Specific Comment	149	7.6.3	pp. 349 ff
152				
	Specific Comment	150	8	p. 465, Figure 8-4
153				
	Specific Comment	151	8.1.2.1	p. 371
154				
	Specific Comment	152	8.1.2.1	p. 369, Equation 8-2
155				
	Specific Comment	153	8.1.2.2.1	p. 375
156				
	Specific Comment	154	8.1.2.2.2	pp. 372-373
157				
158	Specific Comment	155	8.1.3.2.1	p. 404
	Specific Comment	156	8.1.2.3.2	p. 379
159				
	Specific Comment	157	8.1.2.4	Table 8-8
160				
161				

	E	F
144	EPA Original Comment	Original Code
145	The Effects Considerations column frequently contains arguments against the conclusion of risk when HQ is greater than 1. Remove the text in the "Effects Considerations" column for TBT. There is insufficient information provided to evaluate the study, and this is not the place for this discussion. Similarly, the discussion should be eliminated for PCBs. This comment also applies to Table 11-2.	Revise
146	For TBT risk to Largescale sucker and Chinook salmon, the risk conclusion of no unacceptable risk is unacceptable. Any LOE with an HQ > 1 should be identified as posing unacceptable risk. Revise this table accordingly. This comment also applies to Table 11-2.	Directed Change
147	Under the exposure considerations column, the BERA states that the diets are not representative for the species under consideration. However, the concentrations in other potential food sources may be greater (or less) than the ones analyzed, and therefore, the "no unacceptable risk" conclusion is unsupported. Revise this table accordingly. This comment also applies to Table 11-2.	Issue
148	For PCBs in tissue, selected LOAEL is not highly uncertain. Uncertainty is within normal range of uncertainty. Also, no mention is made about how well residue concentrations in PH were characterized for each receptor. There are many uncertainties with the limited residue data available for comparison. Revise this table accordingly. This comment also applies to Table 11- 2.	Revise
149	Revise this table to include only the COPCs, the HQs for each LOE, and the locations of HQs > 1. The "Risk Conclusions" summaries for many of the substance and resources include unwarranted conclusions regarding the interpretation of risks, emphasizing only the uncertainties that justify a conclusion of no or minimal risk, e.g., seeming to give more weight to the low concentrations in water compared to measured tissue concentrations. This comment also applies to Table 11-2.	Revise
150		
151	EPA Original Comment	Original Code
152	The risk conclusions presented in the BERA tend to discount the importance of HQs >1 that were calculated for localized areas. The BERA states that localized areas of risk are not indicative of population level risks. These conclusions inappropriately dismiss the utility of the finding in supporting the identification of locations where the COPC concentrations are sufficient to warrant isolation from exposure to fish and other resources. Revise the BERA accordingly.	Revise
153	Figure 8-4 is quite helpful. If possible, provide a similar figure to represent the uncertainty analysis based on fractions of prey for fish, birds, and other mammals.	Clarify
154	The BERA should clearly describe the risk characterization results based on the EPC approach outlined in the problem formulation. Some of this information is only presented in attachments to the BERA.	Revise
155	Why is the HQ for incidental sediment exposure not multiplied by a factor for the portion of the diet in this equation? The equation appears incorrect. See previous comment on this topic, and revise the text accordingly.	Clarify
156	Remove the "SUF" from Equation 8-3. The problem formulation directed all to be evaluated as using the site year-round. If an SUF is to be used, it would not be in the denominator, but a factor applied to the after TRV/FIR/BW. Was a factor different from 1 used in this equation?	Revise
157	Osprey egg data are undergoing data validation. This data can be used to validate the bird egg line of evidence. Further discussion may be required to figure out how to incorporate into process.	Issue
158	Express the bird egg TRV units in the table as mg/kg wet weight in the egg, not as mg/kg body weight/day, as currently given in the table.	Edit
159	Based on no BSAR relationship found by the LWG using Willamette River data, the conclusion here is that the BMF approach is unreliable except for total TEQ, and later is dismissed entirely as a line of evidence. EPA disagrees with this position and believes that the BMF approach should be used to estimate risk and develop PRGs. The "factor" approach is defensible compared to the "regression" approach. This is the same argument used to dismiss relationships between sediment and tissue. The data and analysis used to calculate the BMRs should be submitted for review. However, the BMF of 10 should be used instead of the BMR presented here. Ultimately, osprey egg concentration data will be available to confirm this relationship.	Issue
160	The use of this methodology was addressed by EPA's problem formulation, which stated, "vary prey items probabilistically to identify components associated with the greatest risk within 1-mile segments (progressed as 1/4 mile increments)." The BERA should be revised consistent with the problem formulation.	Revise
161		

	G	H
144	LWG Comment Response	Reviewer
	Please see response to comment 20.	jmk-cdm smith
145		
	Please see response to comments 5, 6, and 7. Regarding the risk conclusions tables, please see response to comment 20.	jmk-cdm smith
146		
	Please see response to comment 104. Regarding the risk conclusions tables, please see response to comment 20. Additional discussion of dietary uncertainties and direction of bias on risk conclusions has been added to the fish dietary risk characterization.	jmk-cdm smith
147		
	The LWG disagrees. The PCBs TRV is uncertain because the derivation includes several studies that EPA directed the LWG to include, despite the fact that these studies do not meet the agreed acceptance criteria for studies to be included in TRV derivation. Pointing out the uncertainties associated with these studies and the resulting conservative nature of the SSD and resulting TRV is critical information for risk managers. Section 7.1.5.1 (fish tissue-residue risk characterization) discusses uncertainty associated with use of maximum concentrations as EPCs when insufficient data were available to calculate UCLs. Please see response to comment 24.	jmk-cdm smith
148		
	Please see responses to comments 5, 6, and 7.	jmk-cdm smith
149		
150		
151	LWG Comment Response	Reviewer
	Please see response to comments 6, 7, and 17.	jmk-cdm smith
152		
	Please see response to comment 104. Additional figures depicting the range of HQs, considering possible data input values, were used on a case-by-case basis in Section 8.1.5.2.	jmk-cdm smith
153		
	Please see response to comment 17. A risk characterization methods section was added as Section 8.1.1. The methods for deriving TTCs and TSCs were expanded in Section 7.2.1.	jmk-cdm smith
154		
	Equation 8-2 is correct. The HQ for sediment is the sediment exposure concentration divided by the TSC, which accounts for incidental sediment ingestion. Exposure from sediment was conservatively assumed to be in addition to the exposure from prev, rather than as a fraction of prev exposure.	jmk-cdm smith
155		
	The requested revision has been made. No SUF other than 1 was used. Note that SUFs were evaluated as part of uncertainty calculations for specific receptors.	jmk-cdm smith
156		
	As documented in the response to comment 49, the BERA has been revised to include recent osprey bird egg data in lieu of modeled data.	jmk-cdm smith
157		
	The units on the bird egg TRV table have been revised in Section 8 and in Attachment 16.	jmk-cdm smith
158		
	As documented in the response to comment 49, the BERA has been revised to include recent osprey bird egg data in lieu of modeled data. The discussion regarding BMFs and BMF uncertainty has been removed.	
159		
	Tables 8-23 and 8-24 present evaluations of uncertainty associated with dietary assumptions. As resolved in the EPA-LWG non-directed comments meeting (LWG 2010b), in cases where worst-case dietary assumptions could result in HQ exceedances where there had been none before or in a large change in the magnitude of exceedance, a probabilistic analysis such as that presented for mink in Figure 8-4 may provide insight into risks associated with different dietary assumptions. The LWG explored the utility of such analyses. Probabilistic analyses for wildlife dietary COPCs are presented in Table 8-24.	
160		
161		

144	Comment Status
	addressed
145	
	not addressed
146	
	not addressed
147	
	not addressed
148	
	partially addressed
149	
150	
151	Comment Status
	partially addressed
152	
	addressed
153	
	partially addressed
154	
	not addressed
155	
	addressed
156	
	addressed
157	
158	addressed
159	
160	
161	

	J
144	CDM Review Comment (page numbers refer to July 2011 clean copy)
	Table 7-46 replaces Table 7-40. The requested text has been removed from it. Table 11-2 was removed.
145	
146	Table 7-46 replaces Table 7-40. TBT has been removed as a COPC for largescale sucker and chinook salmon. TBT is only listed as a COPC for the sculpin. Table 11-2 was removed.
	Table 7-46 replaces Table 7-40. Similar statements remain for the chinook salmon/cadmium receptor/chemical pair, which is noted as being "negligible" risk. Similar rationale for risk conclusions is provided for other receptor/chemical pairs in the risk conclusions section of the table. Table 11-2 was removed.
147	
	Table 7-46 replaces Table 7-40. It has been revised but similar statements remain in the rationale for risk conclusions discussion. Table 11-2 was removed.
148	
	Table 7-46 now has COPC, LOE, HQ but does not provide locations of HQs>1 and retains the interpretation, uncertainties minimizing risk.
149	
150	
151	CDM Review Comment (page numbers refer to July 2011 clean copy)
	The text has been revised and discusses some localized risks but still discounts associated risks to populations. An example is presented on page 448, last paragraph, which discusses TZW exceedances and risks to sculpin populations.
152	
	Figure 8-4 is now 8-16. Similar figures are provided for other receptor/chemical pairs (Figures 8-3 through 8-9).
153	
	This section is now 8.1.3.1 and revisions may not appear to meet the intent of the comment. The methods are now presented in newly added section 8.1.1.
154	
	This is now presented as equation 7-6 on page 359 and is unchanged. There is disagreement on approach.
155	
	This is now presented as equation 7-2 on page 357. The requested change has been made.
156	
	Section 8 now includes the evaluation of egg data.
157	
158	The original table (8-17) is now Table 8-33. The requested edit was made.
159	
160	
161	

	K	L
144	New EPA Comment	New Comment Code
145	The “effects consideration” column has been replaced by a “Rationale for Risk Conclusion” column. As noted above, the discussion still is highly biased against risk.	
146	The higher TRVs for TBT eliminated it as a risk factor for most exposure routes.	
147	The revised table also has revised language. All risks are negligible to low. The rationales continue to emphasize the risk estimates likely overestimate risks.	
148	See previous comments.	
149		
150	See previous comments.	
151	New EPA Comment	New Comment Code
152	The revised conclusion increases the discussion of potential need for action in some localized areas, but maintains the emphasis on site-wide, population-level risks.	
153	Uncertainty probably plots were included for the mammals and birds, but not for fish.	
154	Descriptive paragraphs were added.	
155	The equations were removed and the text revised to simply refer to the equations and approach used for estimating exposure to fish via diet.	
156	As noted the equations have been removed. The discussion states that a SUF of 1 was used for all receptors.	
157		
158		
159	The BMF discussion and approach were removed. The egg LOE relies solely on the site egg data.	
160	The overall probabilistic approach was added, but not only for mink, river otter, bald eagle, and hooded merganser, species considered to one at highest risk. Changing prey is considered for the other species, but only in range-finding exercise to see if going from one extreme to another would alter the HOs.	
161		

	A	B	C	D
162	Comment Type	No.	Section	Page Line(s)
	Specific Comment	158	8.1.2.4	p. 388
163				
	Specific Comment	159	8.1.2.4	p. 387, Table 8-9
164				
	Specific Comment	160	8.1.2.4	p. 389, Table 8-10
165				
166	Specific Comment	161	8.1.3.1.1	Table 8-11
	Specific Comment	162	8.1.4.1	p. 409 [405, text box?]
167				
168				
169	Comment Type	No.	Section	Page Line(s)
	Specific Comment	163a	8.2.2	Table 8-43
170				
	Specific Comment	163b	8.2.2	Table 8-43
171				
172				
173	Comment Type	No.	Section	Page Line(s)
	Specific Comment	163c	8.2.2	Table 8-43
174				
	Specific Comment	163d	8.2.2	Table 8-43
175				
176				
177	Comment Type	No.	Section	Page Line(s)
178	Specific Comment	177	11.2	p. 511
179				
180				
181				
	Specific Comment	178	11.3	p. 515, Lines 4-7
182				
183				
	Specific Comment	197	Attachment 5 -SLERA	Table 2-6
184				
185				
186	Comment Type	No.	Section	Page Line(s)

	E	F
162	EPA Original Comment	Original Code
163	Predicted tissue concentrations for shore bird prey items were based on the food web model. As part of the uncertainty analysis, BSAFs and BSARs should be used to validate the model predictions. The BSAF models for invertebrates closely tied to the sediment may be more predictive and accurate than a food web model. The criteria for developing BSARs were too restrictive for developing relationships (significantly positive slope at a p of 0.05 and an r squared greater than 0.030).	Issue
164	Several of these beach areas do not match up with shorebird sampling areas. Several addition areas can provide estimates where "none" is listed (e.g., LWG 004 at beach area B4). Simply not estimating exposure to shorebirds at all in these areas is unacceptable.	Issue
165	Section 8.1.2.4, Table 8-10 refers to the results of the mechanistic model for predicted shorebird prey concentrations. Tables with the predicted concentrations from the mechanistic model are presented in Table 3-7 from Attachment 3. However, concentrations are only presented for tributyltin ion, Total PCBs and Total DDX. Values for Dioxin/ Furan TEQ, Total TEQ, Aldrin, and Sum DDE, listed in this table as COPCs, are not presented. Were predicted concentrations not calculated for these chemicals? Only average concentrations are presented, with an associated range of values. Include a table showing the predicted concentrations for each sample used in the EPC calculations for all COIs. Since BSAFs were not calculated for modeled contaminants such as PCBs, pesticides, etc., this information is needed to ensure that modeled results are lining up with expected concentrations from other lines of evidence.	Issue
166	Delete the LPAH and HPAH TRVs presented in Table 8-11. Evaluate PAHs using the total PAH TRV of 40 (mg/kg bw/day).	Revise
167	Citing Barnthouse et al. (2009) here is inappropriate because this paper deals with risk assessment offish exposed to PCBs, and for other reasons. This paragraph is repeated throughout this assessment and should be removed entirely from this section.	Revise
168		
169	EPA Original Comment	Original Code
170	The BERA inappropriately discounts the bird egg line of evidence for evaluating risks to osprey and bald eagle. Table 8-43 states that the bird egg TRVs are inadmissible and that the BMF to develop exposure information is highly unreliable. EPA disagrees with this contention based on the following points: 1) The most sensitive endpoint for these contaminants is the developing embryo, and adverse impacts are measured as: eggshell thinning, moisture loss, and embryo death for DDE; and embryo mortality, inhibited development, and sometimes deformities for PCBs and dioxin-like compounds. (Note: DDT is more of a direct toxin to the adult or juvenile bird, so the dietary approach would be more appropriate than the egg approach for DDT.) The most reliable NOAELs and LOAELs for these contaminants have been derived for bird egg tissue concentrations from egg injection studies and nationwide field evaluations correlating 5-year productivity values to DDE and PCB concentrations in eggs. Hatching success studies have also been conducted on embryos collected from the wild. Egg studies focus on measuring concentrations in eggs that are associated with an adverse impact. Eggs are a common endpoint used in risk evaluations in the Great Lakes and other areas. Thus, there is greater field-based empirical information on impacts to ospreys and eagles from these compounds compared to the dietary approach or compared to other field-based evaluations. Useful field data on osprey eggs are also available directly from Portland Harbor.	Issue
171	2) The dietary approach to assessing risk from bioaccumulative compounds (DDE, PCBs, and dioxins) also has uncertainties associated with it that seem to be understated in the draft BERA. For example, there is huge variation in the response of birds to dietary doses of these chemicals. Gallinaceous birds tend to be much less sensitive to measurable impacts from DDE, whereas chickens seem to be more sensitive than wild birds to dioxins. Dietary-based, lab-toxicology studies have to be conducted over the long term in order to feed the test species contaminated prey items and provide sufficient time to allow buildup of the chemical, followed by egg laying and hatching to test the most sensitive endpoints. Few toxicology studies can be conducted over the course of a year without introducing variables difficult to control and having uncertainty in the results. Also, the risk assessment based on the dietary approach has the disadvantage of employing a number of mathematical steps using "conservative" parameters, including food and sediment ingestion rate, percent moisture conversions, body weight, site use, exposure scale, and diet composition, each associated with some degree of error. In some cases overly conservative values are used (such as employing chicken parameters for dioxin), thus greatly overestimating risk to wildlife receptors. These additional steps add error to the dietary risk assessment, but are not needed in the more directly measured egg-based approach. The dietary approach for dioxin-like chemicals used by LWG to assess birds is also problematic because it relies on an older 1992 pheasant study where dioxin was injected rather than introduced in the diet, and there was no uncertainty factor used to evaluate risks specific to Portland Harbor species.	Issue
172		
173	EPA Original Comment	Original Code
174	3) The variability surrounding the BMF values is high, especially when compared across species (which is really an inappropriate comparison) such as in Table 3-2 of Attachment 16 of the BERA, but is lower when compared within a species. The BMFs selected for use in the Portland Harbor risk assessment should not be the highest values (i.e., the most conservative values), but rather the values empirically measured for the system. Osprey in the lower Willamette River eat 99% fish; thus, they have a direct link to the river and uptake of contaminants through fish. Evaluations of osprey prey on their wintering grounds have shown no contaminants or only trace levels that are dwarfed by contaminants in prey on their breeding grounds. The BMF values calculated by Henny et al. (2003) and (2008) - 10 for total PCBs, 79 for DDE, and 10 for total TEQ - are the best empirically-based BMFs for the system. Granted, there is certainly a higher degree of error around the BMFs compared to other parameters of the risk assessment. However, the BMFs are fairly robust in that choosing a lower range of BMFs (i.e., representing other species at other sites) would not modify the end result much for either comparing to a TRV or back-calculating from a TRV to obtain a target tissue value for fish that would be protective of osprey. The same BMFs used for osprey should also be used to conduct a risk assessment on eagles that would be using Portland Harbor.	Issue
175	4) EPA considers the data using the egg approach as the "most appropriate for estimating risks to birds from dioxin-like chemicals", as stated in our 2003 guidance document: <i>"Analyses of Laboratory and Field Studies of Reproductive Toxicity in Birds Exposed to Dioxin-like Compounds for Use in Ecological Risk Assessment."</i> This document uses a species sensitivity distribution to evaluate effects concentrations of dioxin-like chemicals across species. This method should be considered for use in the revised BERA.	Issue
176		
177	EPA Original Comment	Original Code
178	Remove the following statement: "Although risk estimates indicate the potential for	Clarify
179	unacceptable risks in the Study Area, some risks are associated with regional rather than Study	
180	Area specific contamination."	
181	Local vs. regional risk was not specifically assessed.	
182	The risk characterization and conclusions are not to be based solely on spatial distribution or frequency of HQ > 1.0, as claimed in the BERA text. The discussion should also consider the magnitude of risk. It is acceptable for LWG, in fact desirable, to describe the spatial pattern and limitations of identified risks, as well as to describe which contaminants are site-wide risks to multiple receptors, pose risks to only one receptor or risks in a limited area or section of the site, or something in between these two extremes. This information is useful to EPA in identifying contaminants that will addressed by the response action. It is not acceptable for the BERA to eliminate contaminants posing unacceptable risk those chemicals for which the magnitude of risk is small (i.e., a hazard quotient only slightly greater than one), or which pose unacceptable risks in only a limited area of the site. It is only within the purview of the EPA risk managers to make the decisions regarding the basis for site remediation, and which chemicals, risks, and locations of risk require remediation.	Directed Change
183		
184	Comparison of maximum detected concentration in fish should include all fish. For example, carp concentrations here are marked with a "NE" meaning not evaluated as a receptor in the ecological risk assessment. Screening all fish insures we are adequately protecting all species with our representative fish for each guild.	Revise
185		
186	EPA Original Comment	Original Code

	G	H
162	LWG Comment Response	Reviewer
163	The FWM is used to predict tissue concentrations, so the empirical tissue concentration data were used to test model performance. We disagree that the BSAR acceptability criteria (significantly positive slope at a p of 0.05 and an $r^2 > 0.030$) are too restrictive. This is a point that, if it was going to be raised, should have been raised in comments on the bioaccumulation modeling report (Windward 2009), which was submitted to EPA on 7-21-09.	jmk-cdm smith
164	This is an incorrect interpretation of the table. Where there was neither a field-collected nor a laboratory-exposed tissue, a dietary exposure was estimated based on a predicted tissue using a BSAR (for those chemicals where there was a relationship between sediment and tissue concentrations).	jmk-cdm smith
165	Predicted concentrations for dioxin/furan TEQ, total TEQ, aldrin, and sum DDE (and all other contaminants whose concentrations were predicted for shorebirds) are provided in Attachment 4, Part D for each shorebird beach sediment sample. Attachment 4, Part A presents summary tables of the predicted shorebird prey tissue concentrations (see Table 7-2 in Attachment 4, Part A).	jmk-cdm smith
166	PAHs and HPAHs were removed from the bird analysis. PAHs were evaluated as total PAHs and benzo(a)pyrene.	jmk-cdm smith
167	Please see responses to comments 3 and 138.	jmk-cdm smith
168		
169	LWG Comment Response	Reviewer
170	Please see response to comment 49.	jmk-cdm smith
171	As indicated in the response to comment 49, the Draft Final BERA has been revised to include recent osprey bird egg data in lieu of modeled data. Uncertainty in the dietary dose methods is discussed in the wildlife risk characterization and risk conclusions sections.	jmk-cdm smith
172		
173	LWG Comment Response	Reviewer
174	As indicated in the response to comment 49, the Draft Final BERA has been revised to include recent osprey bird egg data in lieu of modeled data. The discussion regarding BMFs and BMF uncertainty has been removed.	jmk-cdm smith
175	As indicated in the response to comment 49, the Draft Final BERA has been revised to include recent osprey bird egg data in lieu of modeled data.	jmk-cdm smith
176		
177	LWG Comment Response	Reviewer
178	Discussion of management decisions related to regional risks are restricted to Section 12.0 (Risk Management Recommendations) of the Draft Final BERA.	jmk-cdm smith
179		
180		
181	Please see response to comments 3, 5, 6, and 7.	jmk-cdm smith
182		
183	No change was made to Attachment 5. Please see response to comment 106.	jmk-cdm smith
184		
185		
186	LWG Comment Response	Reviewer

162	Comment Status
	not addressed
163	
	not addressed
164	
	partially addressed
165	
166	addressed
167	addressed
168	
169	Comment Status
	addressed or partially addressed
170	
	addressed or partially addressed
171	
172	
173	Comment Status
	addressed or partially addressed
174	
	addressed or partially addressed
175	
176	
177	Comment Status
178	addressed
179	
180	
181	
	partially addressed
182	
183	
	not addressed
184	
185	
186	Comment Status

	J
162	CDM Review Comment (page numbers refer to July 2011 clean copy)
	Edits were not made the address this comment. There was disagreement on the technical approach.
163	
	It appears as though no revisions were made to address this comment. There was disagreement on the interpretation.
164	
	The requested revisions were not made in the main body of the BERA but were provided in the attachment.
165	
166	requested revision made to table (now Table 8-9).
	reference to Barnthouse was removed from Section 8
167	
168	
169	CDM Review Comment (page numbers refer to July 2011 clean copy)
	Use of osprey egg data in the revised BERA may address this comment in part or full.
170	
	Use of osprey egg data in the revised BERA may address this comment in part or full.
171	
172	
173	CDM Review Comment (page numbers refer to July 2011 clean copy)
	Use of osprey egg data in the revised BERA may address this comment in part or full.
174	
	Use of osprey egg data in the revised BERA may address this comment in part or full.
175	
176	
177	CDM Review Comment (page numbers refer to July 2011 clean copy)
178	This statement has been removed.
179	
180	
181	
	The opening paragraph of this section has been revised to indicate that it includes a review of the magnitude and extent of risks; however, the document does not clearly identify risks by location to show localized risks.
182	
183	
	No changes were made to this table (which was assumed to be 3-6 and not 2-6 as referenced in the comment.
184	
185	
186	CDM Review Comment (page numbers refer to July 2011 clean copy)

	K	L
162	New EPA Comment	New Comment Code
	There was no change in the calculations or use of BSAFs or BSARs.	
163		
	There was no apparent change in the beach EPC estimates for the beaches. Note that the concentrations of some substances were modeled for the beaches with no measured data.	
164	Table 7-2 of Attachment 4 now includes all of these substances. The average and range of the estimated concentrations are presented.	
165		
166	Done.	
167	Done.	
168		
169	New EPA Comment	New Comment Code
	This comment seems to have been addressed.	
170		
	The revised BERA egg LOE relies solely on the bird egg measurements (from the five osprey eggs).	
171		
172		
173	New EPA Comment	New Comment Code
	The BMF approach is no longer used in the revised BERA.	
174		
	This report is cited, but only as additional information on the uncertainties in the TRVs. Overall, the revised BERA includes the egg exposure LOE as an important LOE.	
175		
176		
177	New EPA Comment	New Comment Code
178		
179		
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182		
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185		
186	New EPA Comment	New Comment Code

	A	B	C	D
187	Specific Comment	199	Attachment 5 -SLERA	Table 4-2
188				
189	Comment Type	No.	Section	Page Line(s)
190	Specific Comment	201	Attachment 5	p. 12
191				
192	Comment Type	No.	Section	Page Line(s)
193	Specific Comment	205	Attach. 9, Section 7.1.3	Table 7-5 and TRVs presented in Attach. 9.
194	Specific Comment	206	Attach. 12	Table 3-3
195	Specific Comment	207	Attach. 12	Table 3-4
196	Specific Comment	208	Attachment 14, Section 2	3
197				
198	Comment Type	No.	Section	Page Line(s)
199	Specific	209	Attachment	3
200	Comment		14, Section 2	
201				
202				
203				
204				

	E	F
187	Each fish receptor is given a specific diet as outlined in Table 4-2. Due to the uncertainty in knowing what species different fish are feeding on, the Problem Formulation gave specific direction on how to move forward with the fish dietary evaluation. "Include realistic representations of sculpin or smallmouth bass home range (500 to 1/4 mile on one side of the river). For sculpin and smallmouth bass, use a back calculation of the fish dietary risk equation to calculate an acceptable tissue concentration in prey for the protection of fish using the dietary equation, and acceptable dietary dose using EPOA direction on dietary TRVs." This analysis was to be specific to small home range fish and in doing so "will provide information about protection of larger home range omnivorous and insectivorous fish..." Acceptable tissue concentrations were to be calculation and applied to all benthic prey including (for both species) field and laboratory clams, lab worms, crayfish and sculpin. Instead, the bass evaluation is limited to worms, crayfish and sculpin.	Revise
188		
189	EPA Original Comment	Original Code
190	The procedure used to calculate ingested dietary dose in the refined screen should be more clearly described. According to the EPA problem formulation, the refined screen should be performed as was the dietary screening done in the SLERA (i.e. using NOAEL ingested dose toxicity values), with the option of using species specific home range data in the refined screen. The intent of this refined screen procedure was to identify portions of the site for a given COPC that could be eliminated from further dietary risk analyses in the BERA. The correct ingested dose calculation was given as Equation 1 on page 40 of the EPA problem formulation. It called for summing ingested doses from sediment and prey into a single ingested dose value for use in risk estimates. This equation is not presented in Attachment 5; risks appear to have been calculated separately for ingestion of prey and incidental ingestion of sediment, assuming the ingested dose from the other contaminant source was zero. The total ingested dose from prey and sediment combined is what determines unacceptable risk. Results of the dietary dose refined screens for fish, mammals and birds should clearly show how the ingested doses were calculated, or the analyses repeated if necessary to ensure that the sum of the doses from prey and incidentally ingested sediment were used in the refined screen to estimate risks.	Revise
191		
192	EPA Original Comment	Original Code
193	There appears to be a little confusion regarding the lindane fish tissue TRV. The EPA-calculated 5th and 10th percentile-based TRVs were 0.06 mg/kg and 0.24 mg/kg, respectively. The table gives the correct SLERA screening value of 0.023 mg/kg, but an incorrect LOER concentration of 0.2 mg/kg (correct LOER is 0.14 mg/kg for rainbow trout [Ramamoorthy 1985]). If the LOER is actually a rounded version of the 10th percentile TRV of 0.24 mg/kg, it should be placed in the correct column of the table, and the lindane in fish data rescreened to determine if lindane is a chemical of concern in one or more fish species in the BERA. The 5th percentile value of 0.06 mg/kg should also be entered into the table and used in the BERA as appropriate.	Clarify
194	The HQ evaluation for white sturgeon stated that COPCs that only exceeded the HQ for sediment ingestion, i.e., had no prey item that had a HQ >1, were excluded from further consideration. The ingested dietary doses from sediment and prey should first be summed, then a single hazard quotient should be calculated. HQs for sediment should not be summed; <u>only the ingested doses should be summed.</u>	Revise
195	The data in Table 3-4 indicate that the sum of the HQs for copper for clam and sediment and for stomach content and sediment were greater than 1. However, copper was eliminated from further consideration. It should be retained based on a HQ greater than 1.	Revise
196	Table 2-1 summarizes the COPCs included in the dietary TRV review. TRVs used in the BERA are presented in the appropriate section of Appendix F. On April 11, 2008, EPA provided the LWG with recommended TRVs for use in the BERA. This set of TRVs included dietary fish TRVs for PCBs and DDT. The BERA should include fish dietary TRVs for PCBs and DDT as presented in Table 2 of EPA's April 11, 2008 TRV document.	Revise
197		
198	EPA Original Comment	Original Code
199	Table 2-1 summarizes the COPCs included in the dietary TRV review. TRVs used in the BERA	Revise
200	are presented in the appropriate section of Appendix F. On April 11, 2008, EPA provided the	
201	LWG with recommended TRVs for use in the BERA. This set of TRVs included a bird dietary	
202	TRV for total PAHs but not for high and low molecular weight PAHs. The risks to birds based	
203	on dietary exposure to PAHs should be evaluated using the total PAH TRV presented in Table	
204	3 of 2 of EPA's April 11, 2008 TRV document.	

	G	H
187	No change was made to the text. As resolved in the EPA-LWG non-directed comments meeting (LWG 2010b), species-specific screening is appropriate for the Draft Final BERA. The prey species used in the dietary analysis for each fish receptor are listed in Table 4 of the Problem Formulation. Only the identified prey or the most reasonable surrogate were used for each receptor. Screening based on different prey assumptions does not affect the outcome of the risk assessment for any receptor because COPCs identified based on non-prey do not result in potentially unacceptable risks when realistic prey assumptions are used in the Draft Final BERA.	jmk-cdm smith
188		
189	LWG Comment Response	Reviewer
190	Language was revised in Attachment 5 (Section 4.1) to state explicitly that maximum TTC HQs and maximum TSC HQs were summed. EPA agreed that the TTC and TSC approach was acceptable for screening and risk evaluation in the BERA (please see response to comment 201).	jmk-cdm smith
191		
192	LWG Comment Response	Reviewer
193	No changes were made in response to this comment. As documented in the attachment to EPA's 1-23-09 letter to LWG (EPA 2009), the Ramamoorthy (1985) behavioral LOAEL was rejected for inclusion in TRV derivation. The lowest LOAEL was 0.2 mg/kg ww as reported by Schimmel et al. (1977). Too few acceptable studies were available to derive a 5 th or 10 th percentile TRV following the EPA-LWG agreed-upon TRV derivation methods, so none are presented. The November 20, 2008 TRV reconciliation tables (LWG 2008) discussed between the LWG and EPA list this same lindane TRV of 0.2 mg/kg ww presented in Attachment 9. As EPA made no comments on the lindane TRV presented in the November 20, 2008 TRV reconciliation (LWG 2008), this TRV was accepted as final. Additionally, please see response to comment 47.	jmk-cdm smith
194	In the Draft Final BERA a single dietary HQ was calculated as the sum of sediment and prey HQs for all steps of the risk characterization. However, when stomach contents data were used, sediment HQs were not included in the total HQ because any incidentally ingested sediment would have been included in the sample. Please also see response to comment 128.	jmk-cdm smith
195	The LWG has made the requested revision.	jmk-cdm smith
196	Please see response to comment 198.	jmk-cdm smith
197		
198	LWG Comment Response	
199	The LWG has made the requested change. The TRV used for LPAHs, HPAHs, and total PAHs in	jmk-cdm smith
200	the Draft BERA has been compared to only the total PAH EPC for birds. Risks associated with	
201	LPAH and HP AH mixtures have not been assessed separately from risks associated with total	
202	PAHs.	
203		
204		

	not addressed
187	
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189	Comment Status
	addressed
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192	Comment Status
	not addressed
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	not addressed
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	addressed
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199	not addressed
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	J
	No changes were made to the table or the associated text of the SLERA and refined screen.
187	
188	
189	CDM Review Comment (page numbers refer to July 2011 clean copy)
	Text was revised in Section 4.0 of Attachment 5 to indicate tissue and sediment concentration exceedances were summed.
190	
191	
192	CDM Review Comment (page numbers refer to July 2011 clean copy)
	Revisions were not made in response to this comment. There is disagreement on the technical approach.
193	
	This is now Table 3-1 in the Attachment. The revised table differentiates the two approaches and keeps them separate, with footnotes provided. The revision to approach was not completed as requested since there was disagreement in the technical approach.
194	
195	This is now Table 3-2. Copper has been retained as recommended in the comment.
	Following discussion with Burt at the BERA team meeting in Portland, Burt has been reviewing the alternative TRVs as presented by LWG in the BERA, including those ofr DDT and PCBs. The Attachment has not been revised in response to this comment and Table 7-20 of the main text does not present dietary TRVs for PCBs or DDT.
196	
197	
198	
199	Following discussion with Burt at the BERA team meeting in Portland, Burt has been reviewing the alternative TRVs as presented by LWG in the BERA, including those ofr DDT and PCBs. The Attachment has not been revised in response to this comment.
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	K	L
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189	New EPA Comment	New Comment Code
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192	New EPA Comment	New Comment Code
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